UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:18-op-45090 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:17-op-45004 (N.D. Ohio)

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

DECLARATION OF KELLY A. MOORE IN SUPPORT OF RITE AID OF MARYLAND'S MOTION FOR SUMMARY JUDGMENT

I, Kelly A. Moore, declare as follows:

1. I am a partner at the law firm of Morgan, Lewis & Bockius LLP and counsel to Defendant Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid").

2. I make this declaration to place before the Court certain materials relied on in Rite Aid of Maryland's Motion for Summary Judgment;

3. Attached as **Exhibit A** is a true and correct copy of excerpts from the transcript of the deposition of Christopher Belli, which was held on December 20, 2018, in the above-captioned case.

4. Attached as **Exhibit B** is a true and correct copy of excepts from the expert report of Dr. Anupam B. Jena, submitted on behalf of Rite Aid on May 10, 2019, in the above-captioned case.

5. Attached as **Exhibit C** is a true and correct copy of excerpts from the transcript of the deposition of James Rafalski, which was held on May 13-14, 2019, in the above-captioned case.

6. Attached as **Exhibit D** is a true and correct copy of excerpts from the transcript of the deposition of Larry Ringgold, which was held on January 24, 2019, in the above-captioned case.

7. Attached as **Exhibit E** is a true and correct copy of excerpts of Rite Aid of Maryland, Inc.'s Second Supplemental Objections and Answers to Plaintiffs' First Set of Interrogatories Nos. 2, 4-10, 12-15, 17-18, 20, 23-28, 30, 32-33, and 35, which was filed on January 25, 2019, in the above-captioned case.

8. Attached as **Exhibit F** is a true and correct copy of excerpts from the transcript of the deposition of Getzey Hart, which was held on January 31, 2019, in the above-captioned case.

9. Attached as **Exhibit G** is a true and correct copy of email chains dated September 21-22, 2005, Septemer 30, 2009, and July 11, 2012, that were produced in discovery in this matter with the Bates numbers Rite_Aid_OMDL_0047171-72; Rite_Aid_OMDL_0012516-17, and Rite_Aid_OMDL_0012547-49, respectively.

10. Attached as **Exhibit H** is a true and correct copy of excerpts from the transcript of the deposition of Seth Whitelaw, which was held on May 16-17, 2019, in the above-captioned case.

11. Attached as **Exhibit I** is a true and correct copy of notes from a visit by Deputy Chief from the Maryland Division of Drug Control dated February 4, 2009, which were produced in discovery in this matter with the Bates numbers Rite_Aid_OMDL_0016988-89.

12. Attached as **Exhibit J** is a true and correct copy of Maryland Board of Pharmacy Inspection Reports dated June 15, 2012, August, 26, 2010, February 4, 2009, and August 21, 2012, which were produced in discovery in this matter with the Bates numbers Rite_Aid_OMDL_0032614-17; Rite_Aid_OMDL_0032622-28; Rite_Aid_OMDL_0032629-33; and Rite_Aid_OMDL_00326784-87, respectively.

13. Attached as **Exhibit K** is a true and correct copy of closing inventory on November 7, 2014, which was produced in discovery in this matter with the Bates numbers Rite_Aid_OMDL_0032602 respectively.

14. I declare under penalty of perjury that the foregoing is true and correct.

Executed this 28th day of June, 2019.

__/s/ Kelly A. Moore_____

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Exhibit A

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

Case No. 1:17-MD-2804

Hon. Dan A. Polster

APPLIES TO ALL CASES

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED
DEPOSITION OF: CHRISTOPHER BELLI
DATE: December 20, 2018
TIME: 9:35 a.m. to 12:05 p.m.

PLACE: 201 North Franklin Street
Suite 3400
Tampa, Florida

PURSUANT TO: Notice by counsel for Plaintiffs for purposes of discovery, use at trial or such other purposes as are permitted under the Ohio Rules of Civil Procedure

BEFORE: LISA A. SIMONS-CLARK, RMR, CRR
Notary Public, State of Florida at Large

Pages 1 to 210

there. Do you see that?
A. Yes.
Q. It says DC 10 is a Wholesale Distributor for Rite Aid corporation and is engaged in the "Wholesale Distribution" of Prescription Drugs and Devices which, for the purposes of this criteria, means distribution of Prescription Drugs and Devices to persons other than a consumer or patient and includes the offer to sell; deliver; offer to deliver; give away; or transfer, whether by passage of title, physical movement, or both. Do you see that?
A. Yes.
Q. Do you understand that DC -- Rite-Aid's DC 10 was a wholesale distributor?
A. To our internal -- they're inner company sales, so we only ship to our own stores.
Q. Okay. But for the purposes of shipping to Rite-Aid's own stores, you understood that the Perryman facility was a distributor under the Controlled Substances Act?
MS. McENROE: Objection to form.
THE WITNESS: We were a distribution center that were supplying product to our internal stores.
BY MR. PIFKO:

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-OP-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804

EXPERT REPORT OF DR. ANUPAM B. JENA, MD, PhD

May 10, 2019

24. Given the potential for abuse and likelihood of dependence of different opioid products, these drugs are covered under the Controlled Substances Act (CSA). The CSA was enacted in 1971 to "improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances."[10] Under the CSA, controlled substances are divided into five schedules based on whether the substance has an accepted medical use in the United States, its abuse potential, and the likelihood of dependence.[11] Schedule I controlled substances have no accepted medical use in the United States and a high potential for abuse (e.g., heroin, ecstasy), while schedule V substances have the lowest potential for abuse.[12] Most licit opioids are schedule II substances (e.g., oxycodone, morphine, opium), while some are schedule III or even schedule V.[13] Schedule III drugs have a lower potential for abuse than schedule II drugs.[14]

25. [redacted][15]

[10] Gabay, Michael, "The Federal Controlled Substances Act: Schedules and Pharmacy Registration," *Hospital Pharmacy*, 2013, Vol. 48, No, 6, 2013, pp. 473-374, at p. 473.

[11] United States Department of Justice, Drug Enforcement Administration, Diversion Control Diversion, "Controlled Substance Schedules," December 2018, available at https://www.deadiversion.usdoj.gov/schedules/, accessed April 2, 2019.

[12] *Id*.

[13] *Id*.

[14] *Id*.

[15] [redacted]

26. Rite Aid Mid-Atlantic never distributed schedule II drugs. While pure hydrocodone and HCPs are both currently schedule II substances, the DEA rescheduled HCPs from schedule III to schedule II on October 6, 2014.[16] At this time, when HCPs were moved to the higher risk schedule II, Rite Aid Mid-Atlantic discontinued distribution of HCPs.[17] As seen in this exhibit, buprenorphine, typically used to treat opioid dependence, is a schedule III substance, while codeine forms are schedule II, III or V depending on the quantity of the narcotic in the drug. The rest of the opioids are schedule II substances (dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, methadone, meperidine, morphine, opium, oxycodone, oxymorphone, tapendatol). With the exception of buprenorphine and methadone, which are used to treat opioid addiction, the other twelve opioids in **Exhibit 1** are used to treat pain, with slightly different uses depending on the substance.

27. Opioids differ in their potency. To assist physicians with prescribing opioids and to provide a standard way of measuring quantities across opioids, an "opioid conversion factor" has been developed, and has become a standard means of measuring quantities of opioids.[18] This factor is designed to convert the quantity of each drug into units that are equivalent to milligrams of morphine, or morphine milligram equivalents ("MME"). The MME conversion factor is shown in **Exhibit 1**. As can be seen in the exhibit, the conversion factor varies by strength for some opioids. Drugs with higher conversion factors are more potent. For example, the MME conversion factor is equal to 1 for hydrocodone and 1.5 for oxycodone.[19] This means that 10 mg of hydrocodone is equivalent to 10 mg of morphine, but 10 mg of oxycodone is equivalent to 15 mg of morphine. In other words, oxycodone is 50 percent more potent than hydrocodone.

28. An alternative measure that does not account for potency is "dosage units." For pills, one pill is one dosage unit. For example, a 10 mg hydrocodone pill is one dosage unit, as is a 10 mg oxycodone pill, regardless of the fact that oxycodone is more potent than hydrocodone.

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16 United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, "Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II," 79 FR 49661, August 22, 2014, available at https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm, accessed April 4, 2019 (hereafter, "DEA, Rescheduling of Hydrocodone Combination Products (August 2014)").

17 [redacted]

18 United States Department of Health and Human Services, Centers for Disease Control and Prevention, "Calculating Total Daily Dose of Opioids for Safer Dosage."

19 *Id*.

IV. RITE AID MID-ATLANTIC MAINTAINED SUBSTANTIAL CONTROLS AGAINST DIVERSION OF OPIOIDS

A. Rite Aid Mid-Atlantic maintained controls against diversion

33. Plaintiffs claim that distributors, including Rite Aid Mid-Atlantic, failed to maintain effective controls against diversion of opioids. Diversion of opioids occurs when "legally obtained opioids are transferred from a licit to an illicit channel of distribution or use."[26] In fact, Rite Aid had multiple measures in place to prevent diversion throughout the years at issue, and earlier, and passed numerous inspections conducted by state and federal agencies.[27]

34. One component of maintaining effective controls against diversion is to employ a suspicious order monitoring system (SOM), which Rite Aid Mid-Atlantic did. As an initial matter, it is important to note that the DEA never had explicit requirements for exactly how a suspicious order monitoring system should work and it did not establish a common system across all distributors.[28] As Thomas Prevoznik, Section Chief of Pharmaceutical Investigations at the DEA, testified, there is no one-size-fits-all proposition for SOM systems.[29] Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, noted in his deposition that it was not the DEA's policy to tell distributors whether an order was suspicious or not, as that was a decision that "only" the distributor could make because they

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[26] Jena, Anupam B., et al., "Opioid Prescribing By Multiple Providers in Medicare: Retrospective Observational Study of Insurance Claims," *BMJ*, 348:g1393, 2014, p. 2.

[27] Rite_Aid_OMDL_0014804-74, at 05 and 28; Rite_Aid_OMDL_0047171-72; Rite_Aid_OMDL_0032629-33; Rite_Aid_OMDL_0016988-89; Rite_Aid_OMDL_0012516-17; Rite_Aid_OMDL_0032622-28; Rite_Aid_OMDL_0032620; Rite_Aid_OMDL_0032621; Rite_Aid_OMDL_0012547; Rite_Aid_OMDL_0032618-19; Rite_Aid_OMDL_0032614-17; Rite_Aid_OMDL_0036784-87; and Rite_Aid_OMDL_0032612-13.

[28] This notion was confirmed by one of Plaintiffs' suspicious order monitoring experts in in his expert report. Rafalski Report, pp. 12-13 ("Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ('SOMS'), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done."). *See also*, Deposition of Kyle Wright, Unit Chief of the Targeting and Analysis Section at the DEA, February 28, 2019 (hereafter, "Wright Deposition"), pp. 128-129 ("Q. And it was understood, with the move toward the Suspicious Order Monitoring Program, that not every company would necessarily have the exact same type of program; fair? […] A. Yes, ma'am. Q. And, in fact, DEA wanted companies to be able to adopt their particular programs to whatever the particular clients were that they might service, correct? […] A. Yes, ma'am.").

[29] Deposition of Thomas Prevoznik, Section Chief of Pharmaceutical Investigations at the DEA , April 17-18, 2019 (hereafter, "Prevoznik Deposition"), p. 446 ("Q. Is it fair to say that a SOMs systems is not a one-size-all proposition, one-size-fits-all proposition? A. Correct.").

enforcement and Boards of Pharmacy regarding internal theft and arrest warrants being issued.[50]

B. Rite Aid Mid-Atlantic's policies and procedures limited the risk of diversion and demonstrated effectiveness

39. The following five facts documented in this section are consistent with the effectiveness of Rite Aid Mid-Atlantic's previously described anti-diversion measures, its overall policy on the distribution of schedule II drugs, and its distribution structure: Rite Aid Mid-Atlantic (1) passed every state and federal inspection, suggesting the appropriateness of its anti-diversion measures, (2) never distributed schedule II drugs, a more potent class of opioids, (3) distributed only to Rite Aid pharmacies, which permitted an additional layer of monitoring, (4) accounted for [redacted] of opioids distributed to Cuyahoga and Summit Counties, and (5) had stable opioid shipment volumes during the period at issue, despite the fact that total opioid distribution to Cuyahoga and Summit Counties was increasing over the period.

1. Rite Aid Mid-Atlantic passed every inspection

40. From 2005-2014, the DEA audited Rite Aid Mid-Atlantic's controls against diversion, including its suspicious order monitoring system, in four unannounced audits and found no deficiencies.[51] Similarly, the State of Maryland performed several inspections of the facility during the relevant time period, including anti-diversion methods, and also found no deficiencies.[52] For example, the State of Maryland's Board of Pharmacy examined Rite Aid Mid-Atlantic's inventory control measures in 2010 and again in 2012 and found that it had a "security system that provides protection against theft and diversion" and an "inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting."[53] In addition, in both inspections, the State of Maryland

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50 Rite_Aid_OMDL_0037816-51 ("Anatomy of a Pharmacy Case" presentation by Andy Palmer), at 34-48.

51 Rite_Aid_OMDL_004717-72; Rite_Aid_OMDL_0012516-17; Rite_Aid_OMDL_0032620; Rite_Aid_OMDL_0032618-19; and Rite_Aid_OMDL_0032602. The only recommendations were to "repair wire mesh on cage" and to "add a camera directly over the area where we receive and break down the cage receipts." *See* Rite_Aid_OMDL_0032620.

52 The only recommendation from the State of Maryland was to identify a carrier tracking number when reporting a vendor shortage. Rite_Aid_OMDL_0032629-33; Rite_Aid_OMDL_0016988-89; Rite_Aid_OMDL_0032622-28; Rite_Aid_OMDL_0032614-17; and Rite_Aid_OMDL_0036784-87.

53 Rite_Aid_OMDL_0032622-28 at 25; and Rite_Aid_OMDL_0032614-17 at 16.

found that Rite Aid Mid-Atlantic "maintains a system and records for the mandatory reporting to the Board, the FDA and where applicable the DEA, significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring or has occurred."[54] Similarly, the State of Maryland's Division of Drug Control found that Rite Aid Mid-Atlantic "provide[d] effective controls and procedures to guard against theft and diversion" in 2009 and 2012.[55] **Exhibit 2** summarizes the findings of the inspections from the DEA and the State of Maryland.

[54] Rite_Aid_OMDL_0032622-28 at 26; and Rite_Aid_OMDL_0032614-17 at 16.
[55] Rite_Aid_OMDL_0032629-33 at 31; and Rite_Aid_OMDL_0036784-87 at 85.

Exhibit 2
Summary of Rite Aid Mid-Atlantic Inspections
2005-2014

Inspection Date	Inspector	Actions Required/Recommended	Relevant Findings
September 21, 2005	DEA	None	"…no words of advice for the Staff for improvement. It was a flawless audit."
February 4, 2009	Maryland Division of Drug Control	"Please identify carrier tracking number [when reporting a vendor shortage]."	
September 30, 2009	DEA	"…add a camera directly over the area where we receive and break down the cage receipts."	"Everything we saw meets the requirement of what we came to see. I'm happy, very happy."
August 26, 2010	Maryland Board of Pharmacy	None	"Facility ships only to its Rite Aid stores."
July 10, 2012	DEA	"Asked URS to repair wire mesh on cage."	"Both DEA inspectors are very impressed and pleased to see that Rite Aid demonstrates its due diligence by having an excellent excessive order monitoring system."
August 16, 2012	Maryland Board of Pharmacy	None	"Reviewed training documentation, temp logs, invoices, and written policies/procedures."
August 21, 2012	Maryland Division of Drug Control	None	"This facility has a good system for receipt and accountability of CDS [controlled dangerous substances]."
November 17, 2014	DEA	None	[No longer distributing HCPs]

Sources:
[A] Rite_Aid_OMDL_0047171-72.
[B] Rite_Aid_OMDL_0032629-33; and Rite_Aid_OMDL_0016988-89.
[C] Rite_Aid_OMDL_0012516-17.
[D] Rite_Aid_OMDL_0032622-28.
[E] Rite_Aid_OMDL_0032620; Rite_Aid_OMDL_0032621; Rite_Aid_OMDL_0012547; and Rite_Aid_OMDL_0032618-19.
[F] Rite_Aid_OMDL_0032614-17.
[G] Rite_Aid_OMDL_0036784-87.
[H] Rite_Aid_OMDL_0032602; and Rite_Aid_OMDL_0032612-13.

41. On July 10 and 11 of 2012, two inspectors from the DEA conducted an unannounced audit of Rite Aid Mid-Atlantic.[56] According to Rite Aid Mid-Atlantic's notes of the audit, both of the DEA inspectors were "very impressed and pleased to see that Rite Aid demonstrate[d] its due diligence by having an *excellent* excessive order monitoring program."[57] According to testimony from DEA employees, registrants can rely on guidance from DEA field agents.[58] In the case of Rite Aid Mid-Atlantic, that means accepting the positive feedback from the unannounced DEA audits and not implementing any additional mechanisms to its suspicious order monitoring system. The DEA inspectors also "mentioned that the DEA is taking a harder look at all distributors to ensure that order monitoring processes are in place and effective."[59] Even with the additional scrutiny, the DEA inspectors were pleased with Rite Aid Mid-Atlantic's system and found no deficiencies.

2. Rite Aid Mid-Atlantic did not distribute schedule II opioids

42. Rite Aid Mid-Atlantic never distributed schedule II drugs. From 2006-2014, the only opioids Rite Aid Mid-Atlantic distributed were HCPs.[60] HCPs were schedule III drugs until they were moved to schedule II in October 2014.[61] Rite Aid Mid-Atlantic stopped distributing HCPs when the DEA rescheduled HCPs to schedule II after concluding that HCPs had a higher potential for abuse than previously believed.[62] I understand that Rite Aid Mid-Atlantic stopped distributing all narcotics in November 2014.[63]

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56 Rite_Aid_OMDL_0032618-19.

57 *Id*.

58 Prevoznik Deposition, p. 461 ("Q. DEA headquarters expects a registrant to listen to the information it receives from DEA field office personnel, true? […] A. Yeah. It depends what they are asking, sure. Q. Okay. And the registrants who are visited by DEA field office personnel can rely on the information that they receive from DEA field division personnel regarding SOMs systems, true? […] A. Yeah, they get guidance."); and Wright Deposition pp. 231-232 ("Q. And based on your experience, you think it would be fair for a registrant to rely on guidance that the registrant received from DEA agents out in the field? […] A. If you make the phone call, you expect to receive a -- an answer. And if you're making that phone call, I think you would rely on the information an then put it together with ever -- other factors that are known to you to make that decision. Q. Okay. And that's the registrant receiving information from DEA, relying on that, and then acting? A. Yes, sir.").

59 Rite_Aid_OMDL_0032618-19.

60 [redacted] and ECF No. 693 at 3 ("Accordingly, the Special Master RULES as follows. Defendants shall produce discovery related to all opioid products that are or ever were classified as Schedule II under the Controlled Substances Act.").

61 DEA, Rescheduling of Hydrocodone Combination Products (August 2014).

62 [redacted]

63 Rite_Aid_OMDL_0032602.

pharmacies that had in place policies and procedures to prevent diversion.[70] This is not necessarily true of all distributors; many distribute to unaffiliated pharmacies with varying degrees of pharmacy-level policies and procedures.

46. Plaintiffs' experts focus on total distributions of opioids, essentially assuming that every opioid pill sold—whether through a "pill mill" or a Rite Aid pharmacy—had an equivalent chance of diversion (and thus inflicted equal harm). As an expert in medicine, economics, and health policy research, it is my opinion that this assumption is false. Some distribution channels—such as rogue internet pharmacies—had a risk of diversion that was significantly higher than diversion of pills sold through chain pharmacies. Any reliable analysis of the harms caused by distribution of opioids must necessarily consider the varying risks of diversion through different channels of distribution.

47. Rite Aid Mid-Atlantic's distribution to only Rite Aid chain pharmacies is particularly important since Rite Aid Mid-Atlantic never distributed to rogue Internet-based pharmacies, a well-known channel for diversion of opioids. My own research has examined the rise in popularity of obtaining controlled prescription medications on the Internet without a valid prescription and the necessity of increased efforts to curb illegitimate Internet-based pharmacies.[71] Furthermore, the DEA focused its efforts on rogue Internet pharmacies and rogue pain clinics, to which Rite Aid Mid-Atlantic never distributed.[72] A presentation by the DEA explicitly states that chain pharmacies, such as those to which Rite Aid Mid-Atlantic distributes, are not rogue pharmacies.[73]

48. Rite Aid Mid-Atlantic also never distributed to opioid "pill mills." Plaintiffs' expert Dr. Gruber created a database of such prosecutions.[74] Of the 165 total prosecutions, only 23

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70 *See*, e.g., Rite_Aid_OMDL_0044309-17 ("Procedures for Validation and Dispensing of High Alert Controlled Substances"); Rite_Aid_OMDL_0044361-62 (memo re: "Validation and Dispensing High Alert Controlled Substances"); Rite_Aid_OMDL_0044387 ("Suspicious DEA Pharmacy Activity" memo).

71 Jena, et al. (2011); and Jena and Goldman (2011).

72 Rannazzisi Deposition, p. 197 ("Q. Sir, is it fair that DEA focused its attention in the 2005 to, say, 2009 era on rogue Internet pharmacies? […] A. I would say the -- up until at least 2008, after the Ryan Hate [sic] Act was passed, it pretty much shut down most of the Internet pharmacies and there was a switch to rogue pain clinics. There has always been rogue pain clinics but the rogue pain clinics got -- increased in numbers quite a bit right after Ryan Hate [sic] was passed."); and Rannazzisi Deposition, Exhibit 10.

73 Rannazzisi Deposition, Exhibit 10.

74 "DOJ Prosecutions of Opioid Pill Mills.xlsx" from backup materials to Gruber Report.

involved establishments categorized as a "pharmacy" and only one of these appear to be related to a national chain pharmacy, which was not Rite Aid.[75] The remaining 142 prosecutions were primarily of clinics and medical offices, i.e. pill mills.[76]

4. Rite Aid Mid-Atlantic accounts for [redacted] of opioid distribution in Cuyahoga and Summit Counties

49. Rite Aid Mid-Atlantic distributed a very small share of all opioids into Cuyahoga and Summit Counties. **Exhibit 3** compares the total shipments of opioids to Cuyahoga and Summit Counties with Rite Aid Mid-Atlantic's shipments.[77] Because opioids differ in potency, shipments are measured in MMEs. Throughout the period January 2006 to December 2014, Rite Aid Mid-Atlantic accounted for [redacted] percent of MMEs distributed into Cuyahoga and Summit Counties. Furthermore, and importantly, Rite Aid Mid-Atlantic's share of MMEs distributed into the counties declined over time and eventually fell to **zero** after the rescheduling of HCPs to schedule II in October 2014, since Rite Aid Mid-Atlantic stopped distributing HCPs when they became schedule II and stopped distributing all narcotics in November 2014.[78] In contrast, as I discuss below, MMEs dispensed to these counties from other distributors increased during this period.

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75 The address provided for Eric Tingley is associated with another national chain pharmacy in Connecticut. *Id.*

76 *Id.*

77 [redacted]

78 [redacted]; and Rite_Aid_OMDL_0032602.

Exhibit 3
Distribution of Opioid Products to Cuyahoga and Summit Counties

All Distribution — Rite Aid Mid-Atlantic's Distribution

Notes:

Source:

5. Rite Aid Mid-Atlantic distribution of opioids to Cuyahoga and Summit Counties did not increase like total opioid distribution to Cuyahoga and Summit Counties

50. Dr. Cutler and Dr. Gruber discuss a pattern of increasing opioids shipments nationwide until 2010 in their reports.[79] Dr. Cutler argues that, prior to 2010, "the [opioid] crisis was characterized by large and on-going increases in the shipments of prescription opioids and the rapid increases in mortality associated with prescription opioids."[80] Even though increases in total shipments of prescription opioids do not imply increased diversion, I note the important point that Rite Aid Mid-Atlantic's distribution of opioids into Cuyahoga and Summit Counties

[79] Cutler Report, Section V.A.; and Gruber Report, Section III.
[80] Cutler Report, ¶ 50.

did not follow the same increasing pattern as the total distribution of opioids into Cuyahoga and Summit Counties.

51. **Exhibit 4** compares Rite Aid Mid-Atlantic's distribution of opioids to Cuyahoga and Summit Counties to the total distribution of opioids to these counties for the period 2006 through 2014.[81] To allow for comparison of the trends in distribution, total volume of opioids is calculated as MMEs indexed to the first quarter of 2006. The exhibit shows that Rite Aid Mid-Atlantic's distribution tracks the total distribution through the second quarter of 2008, but then significantly decreases, falling to zero after the rescheduling of HCPs to schedule II in October 2014, when Rite Aid Mid-Atlantic ceased distributing the opioids at issue in this litigation (and only one month prior to when Rite Aid Mid-Atlantic ceased distribution of *all* narcotics in November 2014).[82]

81 [redacted]

82 [redacted]; and Rite_Aid_OMDL_0032602.

Exhibit 4
Distribution of Opioid Products to Cuyahoga and Summit Counties

[redacted]

Source: [redacted]

52. The decrease in Rite Aid Mid-Atlantic's distribution of opioids into Cuyahoga and Summit Counties in part reflects a general shift in distribution from Rite Aid Mid-Atlantic to another Rite Aid distribution center that I understand is not a defendant in this litigation. To account for this shift, **Exhibit 5** compares the sum of Rite Aid's distribution of opioids to Cuyahoga and Summit Counties to the total distribution of opioids to these counties. While the combined Rite Aid shipments of opioids do not significantly fall after the second quarter of 2008, they do not grow as they do for overall distribution and instead fall or stay flat through 2014, when Rite Aid Mid-Atlantic ceased distributing the opioids at issue in this litigation.

Exhibit 5
Distribution of Opioid Products to Cuyahoga and Summit Counties

[redacted]

Notes:
[redacted]

Source:
[redacted]
[B] "Distribution Centers / Ship-to-Locations," *Rite Aid Corporation*, available at http://www.riteaidediservices.com/wp-content/uploads/2018/02/DISTRIBUTION-CENTERS-SHIP%E2%80%93TO-LOCATIONS-Update-20180124.pdf, accessed May 7, 2019.

V. PLAINTIFFS' METHODOLOGY FOR IDENTIFYING SUSPICIOUS ORDERS IS FLAWED AND UNRELIABLE

53. In section IX of his report, titled "Transaction Analysis," Dr. McCann "implemented various approaches to identify transactions meeting specified criteria using the non-public ARCOS Data from 2006 to 2014."[83] In his report, Dr. McCann does not identify these transactions as "suspicious orders," but James Rafalski, Plaintiffs' expert on statutory and regulatory compliance, stated that he "review[ed] five suspicious order methodologies" that "are

[83] McCann Report, ¶ 130.

Exhibit 14
Rite Aid Mid-Atlantic's Share of MMEs Distributed into Cuyahoga and Summit Counties, Total and Flagged by Dr. McCann's "Transaction Analysis"
2006-2014

		MMEs (in Millions)	% of Total MMEs
[A]	All MMEs distributed to dispensers in Cuyahoga and Summit Counties, excluding methadone, buprenorphine, and non-schedule II codeine	[redacted]	[redacted]
[B]	Rite Aid Mid-Atlantic's hydrocodone MMEs distributed into Cuyahoga and Summit Counties	[redacted]	[redacted]
[C]	Rite Aid Mid-Atlantic's hydrocodone MMEs flagged by Dr. McCann under 3x trailing 12 month average method	[redacted]	[redacted]
[D]	Rite Aid Mid-Atlantic's hydrocodone MMEs flagged by Dr. McCann under 3x trailing 12 month average method, but without the all-subsequent-shipments-are-tainted assumption	[redacted]	[redacted]

Notes and Sources:
[redacted] and Master Drug Data Base (MDDB), Copyright 2019, *Clinical Drug Information*, LLC. "Dispensers," as defined by Dr. McCann, include "Buyers whose Business Activity suggests they dispense drugs to patients" (e.g., pharmacies, practitioners, and hospitals/clinics). Master Drug Data Base was used to identify non-schedule II codeine. If a codeine NDC did not appear in Master Drug Data Base, it was assumed to be non-schedule II.
[redacted] This method is with the all-subsequent-shipments-are-tainted assumption.
[redacted], but without the all-subsequent-shipments-are-tainted assumption.

E. Further evidence that Dr. McCann's "transaction analysis" is unreliable

83. To evaluate the validity of a methodology, an economist should perform robustness tests, which Dr. McCann has not done. In this section, I present the results of two very basic tests of his approach. In the first, I apply Dr. McCann's methodology to transactions for selected *non-opioid* drugs that do not have abuse potential and show that it flags large numbers of transactions as being suspicious. This analysis demonstrates that Dr. McCann's approach flags transactions as suspicious regardless of their potential for diversion. In the second, I show that his methodology fails to flag transactions to doctors who are known to have illegally distributed opioids. These tests are further evidence that Dr. McCann's analysis is incapable of distinguishing orders that were suspicious from those that were not.

Exhibit C

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E. RAFALSKI, VOLUME 2, held at Weitz & Luxenburg PC, 3011 West Grand Avenue, Suite 2150, Detroit, Michigan, commencing at 8:25 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

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Q. Okay. And with respect to Mallinckrodt in particular, given those restrictions, is it fair to say that all of the opinions you express in your report are based on materials that you reviewed in connection with this litigation?

A. Yes, sir.

Q. And your opinions are not based on any other information outside of what you've relayed and referred to in your report?

A. Well, it's difficult to -- since I worked the case for a period of years, obviously, that there may be things I know that aren't part of the discovery, but the opinion I wrote is only based on the information contained in my report.

Q. Okay. And do you intend at trial to offer any information or opinions that are based on something other than what you've cited here in this report?

MR. FULLER: Object to form, based on the same basis earlier.

A. If the Touhy letter is in place and it's restricted by the government, then I

would not offer anything outside of what's contained in my report or currently contained in the discovery material.

BY MR. O'CONNOR:

Q. In your report, do you express any opinion as to the adequacy of Mallinckrodt's present day suspicious order monitoring program?

A. I do not believe I do.

Q. Okay. And just so we're clear about the period of time your opinions do relate to, do you have any opinion with respect to Mallinckrodt's suspicious order monitoring program in 2018?

A. I do not.

Q. 2017?

A. I don't think my report references any time period after 2011.

Q. Okay. So fair to say in this litigation, you're not providing any opinion with respect to Mallinckrodt's suspicious order monitoring program after 2011?

MR. FULLER: Form.

A. At the current time based -- I'm sorry.

beginning of the day, right in the morning?

A. I recall I was interviewed or deposed about Walgreens. I don't specifically -- the questions, I don't recall.

Q. Okay. You issued 183 -- 180-some-odd-page report, right?

A. Yes, sir.

Q. And in that, you set forth your opinions, and you told Ms. Swift that all of your opinions are in that report, right?

A. Of the companies that I evaluated, the opinion -- of -- yes.

Q. Yes.

And the bases for those opinions, except insofar as they're based on your own personal experience and knowledge, are in the footnotes to that report, right?

MR. FULLER: I'm going to object, and if I can have a running objection that this is outside my cross.

MR. MATTHEWS: That's fine, you can have your objection, thank you.

MR. FULLER: Thank you.

Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

\- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL NO. 2804
	:	CASE NO. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES:	:	Hon. Dan A. Polster

\- - -

Thursday, January 24, 2019

\- - -

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

\- - -

Videotaped deposition of LARRY RINGGOLD, taken pursuant to notice, was held at Homewood Suites by Hilton 4170 Philadelphia Road, Bel Air, Maryland 21015, beginning at 5:01 p.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter.

\- - -

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time limit on trying to close cases.

Q. Those would be shortage claim cases?

A. Yes.

Q. What was the time limit to close those?

A. I believe we had 48 hours.

Q. And what did you do to close a shortage claim case?

A. Just investigate.

Q. What did you do to investigate?

A. I would start getting information from either Debra Chase, Marian Woods or Keith Frost.

Q. What kind of information would you get from those individuals?

A. Who picked, who was the person that picked it, who was the person that inventoried it at the desk. And from there, [redacted]

[redacted]

Q. So when you have an X in the column closed here on Page 3 of Exhibit-3, what does the X there mean in the closed column?

A. Meaning we were done. Meaning, we close it out on the security side.

Q. Does that mean you found the missing product?

A. On that particular one, I can't -- I could not say yes or no to. But it was closed out on our end.

Q. Where would you find the information about how this was closed out?

A. Repeat that question,

please.

Q. Yes. Maybe it wasn't the best question.

So it's marked closed on this tracking sheet. Where would I find the information about how this particular claim for negative 2 bottles of hydrocodone/APAP went?

A. Where it went? Normally, if I can go back in my memory, I believe when I say closed, meaning it was found.

Q. Was there any record of where the -- where the product was found, besides just the information here that it was closed?

A. I don't remember.

Q. In the next row down, it looks like it's for Store 7766?

A. Yes.

Q. And over in the shortage claim column, it says, One each, and in parentheses, Rx overstock.

Do you see that?

A. I do.

Q. What does that mean?
A. That might have been the area where it was. I don't remember.
Q. Would a positive number in the shortage claim column here represent that the store got an extra unit of whatever the product name was?
A. I don't remember.
Q. Do you still use these sort of weekly investigation tracking sheets?
A. No.
Q. When did you stop using them?
A. Once we stopped doing the drug investigations back in 2014.
Q. So these weekly investigation tracking sheets were only for controlled drugs?
A. I can't remember.
Q. Did you personally fill out these weekly investigation tracking sheets?
A. Yes.
Q. Did anyone else?

briefing with day and night shift associates that work in the cage. I just want to go over a few procedures with the scanning of their badges in and out of the cage. I would like to get with all the cage associates next week.

Do you see that?

A. I do.

Q. What were you referring to here when you wanted -- when you were referring to the procedures about scanning their badges in and out of the cage?

A. We had a few folks that was getting locked in the cage. So what was happening, they wasn't doing a proper swipe. They would swipe in. But to go out, sometimes if you hit it twice, it would think you were still in the cage but you would actually be out.

So I just had to explain to them how to swipe in and out, because we were getting a lot of calls to the front, hey, I'm stuck in the cage. So we had to

Do you see that?

A. I do.

Q. So Marian Wood is saying that you kept a log of all the Rx cage and vault tests, right?

MR. LAVELLE: Object to form. Objection. Vague.

The question is about the e-mails that Mr. Ringgold was not copied on and did not send or receive.

MR. POWERS: John, just objection to form is fine.

BY MR. POWERS:

Q. Mr. Ringgold, did you keep a log of the Rx cage and vault tests?

A. I did not keep a log.

Q. You did not keep a log?

A. No.

Q. Did anyone keep a log of the Rx cage and vault tests?

A. Not a log. I kept a -- an actual report.

Q. So you kept all of the

reports that were generated from the tests?

A. We had to.

Q. What kind of report was generated from these tests?

A. Just to show that the alarms were working and the motion tests were going off.

Q. Was it a written report?

A. It was -- yes. Not really written, but just showed actual motion 1, motion 2, whatever, that it would go off.

And that was part of the DEA compliance.

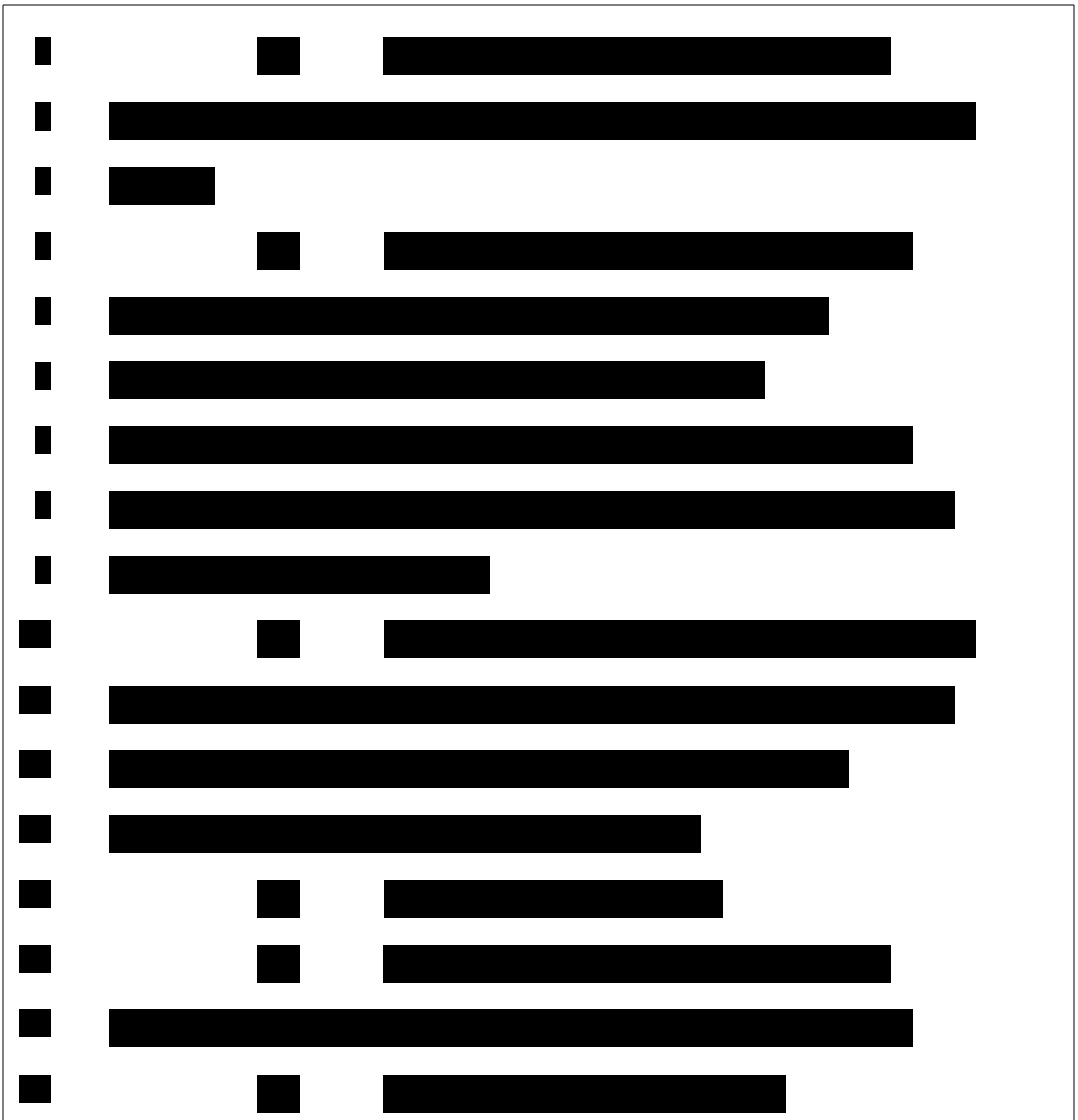
Q. Was that a -- was that, like, a printout or something or --

A. Yes, it was a printout from --

MR. LAVELLE: Wait until the question is finished before you answer it.

THE WITNESS: Yes.

MR. LAVELLE: Otherwise the record is going to be messed up.



Q. What do you have -- what did you say in the next sentence of this e-mail?

A. Shannon started the tote and did go by the pick list order.

Q. And what does that mean?

A. We get an actual pick list

Exhibit E

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: Track One Cases	MDL No. 2804; Case No. 17-md-2804 Judge Dan Aaron Polster

RITE AID OF MARYLAND, INC.'S SECOND SUPPLEMENTAL OBJECTIONS AND ANSWERS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES NOS. 2, 4-10, 12-15, 17-18, 20, 23-28, 30, 32-33, and 35

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center ("Rite Aid of Maryland")[1] supplements its objections and responses to Interrogatory Nos. 2, 4-10, 12-15, 17-18, 20, 23-28, 30, 32, 33, and 35[2] of Plaintiffs' First Set of Interrogatories (the "Interrogatories"), as set out below.

PRELIMINARY STATEMENT

1. These Objections and Answers are made without waiving, or intending to waive, (i) any objections as to the competency, relevancy, materiality, privilege, or admissibility of information or documents provided in response to the Interrogatories; (ii) the right to object on any ground to the use of the information or documents provided in response to the Interrogatories at any hearing or trial; (iii) the right to object on any ground at any time to a request for further

[1] The Interrogatories are directed at Rite Aid Corporation ("RAC"). RAC is no longer a defendant in any of the Track One cases. Rite Aid of Maryland remains a defendant. Accordingly, in the interest of expediency, Rite Aid of Maryland responds as if these Interrogatories are directed at it and not at RAC.

[2] Rite Aid of Maryland served its original responses on July 5, 2018. Rite Aid of Maryland served supplemental responses to Interrogatory Nos. 1, 3, 5, 11, 15-20, 22, 28, 29, 31, and 34 on September 21, 2018.

Rite_Aid_OMDL_0016522; Rite_Aid_OMDL_0016717; Rite_Aid_OMDL_0030099; Rite_Aid_OMDL_0046082; Rite_Aid_OMDL_0046158); Threshold Logs (*see, e.g.*, Rite_Aid_OMDL_0013151; Rite_Aid_OMDL_0013988; Rite_Aid_OMDL_0013972); a proprietary Pharmacy Replenishment System (*see, e.g.*, Rite_Aid_OMDL_0046321); and Above Average Controlled Drug Purchases Checklists, which were modified over time and later became known as Above Average Controlled Drug Purchases Reports (*see, e.g.*, Rite_Aid_OMDL_0046228).

As set forth in Rite Aid of Maryland's policies and procedures, Rite Aid of Maryland maintained and imposed threshold monitoring. During the relevant period, the threshold imposed at the Perryman Distribution Center for all controlled substances was 5,000 dosage units per order, unless a pharmacy had received prior approval from the Government Affairs department at Rite Aid Hqtrs. Corp. to submit orders for a particular controlled substance above the threshold. *See, e.g.*, Rite_Aid_OMDL_0015079 - Rite_Aid_OMDL_0015081. The thresholds for controlled substances and the limited threshold exceptions were posted in the Controlled Drug Cage at the Perryman Distribution Center. *See, e.g.*, Rite_Aid_OMDL_0012501 - Rite_Aid_OMDL_0012502; Rite_Aid_OMDL_0012504 - Rite_Aid_OMDL_0012505; Rite_Aid_OMDL_0032594; Rite_Aid_OMDL_0041875 - Rite_Aid_OMDL_0041876.

If a Rite Aid Pharmacy placed an order for a controlled drug that was above the threshold for that pharmacy, then the order fulfillment personnel in the Controlled Drug Cage at the Perryman Distribution Center did not fill the order as placed. *See id*. Order fulfillment personnel in the Controlled Drug Cage at the Perryman Distribution Center also did not fill orders as placed that were below the threshold if the order appeared high or unusual for that particular pharmacy and pharmacy personnel confirmed that they wanted or intended to order a smaller amount. *See*

id. Orders that were above the threshold and orders that were below the threshold but appeared high or unusual for a particular pharmacy were recorded in the Threshold Log. *See id.*[5]

Personnel at the Perryman Distribution Center conducted due diligence by calling the pharmacy that submitted the order. *See, e.g.*, Rite_Aid_OMDL_0015079 - Rite_Aid_OMDL_0015081. If personnel at the Perryman Distribution Center spoke with personnel at the pharmacy, the conversation was recorded in the Threshold Log. *See id*; *see also, e.g.*, Rite_Aid_OMDL_0013972; Rite_Aid_OMDL_0013819; Rite_Aid_OMDL_0013988; Rite_Aid_OMDL_0013111; Rite_Aid_OMDL_0013151; Rite_Aid_OMDL_0015283; Rite_Aid_OMDL_0015877. Even if the Perryman Distribution Center personnel failed to get in touch with a pharmacy, the above-threshold order was shorted to the threshold before the order was shipped and the date of the order, the product ordered, the amount ordered, the amount shipped, and due diligence conducted by the Perryman Distribution Center were recorded in the Threshold Log. *See id*.

Although personnel at the Perryman Distribution Center had no authority to fulfill an order for a controlled substance above the threshold, a pharmacy could request a threshold increase. Upon such a request, the Government Affairs department analyzed various reports (*e.g.*, purchase records through Store Order History reports generated by Rite Aid's Pharmacy Replenishment

[5] *See also, e.g.*, Rite_Aid_OMDL_0013101; Rite_Aid_OMDL_0013107; Rite_Aid_OMDL_0013111; Rite_Aid_OMDL_0013145; Rite_Aid_OMDL_0013151; Rite_Aid_OMDL_0013818; Rite_Aid_OMDL_0013819; Rite_Aid_OMDL_0013905; Rite_Aid_OMDL_0013916; Rite_Aid_OMDL_0013971; Rite_Aid_OMDL_0013972; Rite_Aid_OMDL_0013986; Rite_Aid_OMDL_0013987; Rite_Aid_OMDL_0013988; Rite_Aid_OMDL_0014021; Rite_Aid_OMDL_0014036; Rite_Aid_OMDL_0014455; Rite_Aid_OMDL_0014486; Rite_Aid_OMDL_0014492; Rite_Aid_OMDL_0015283; Rite_Aid_OMDL_0015349; Rite_Aid_OMDL_0015815; Rite_Aid_OMDL_0015872; Rite_Aid_OMDL_0015877; Rite_Aid_OMDL_0017233; Rite_Aid_OMDL_0017359; Rite_Aid_OMDL_0017417; Rite_Aid_OMDL_0017422; Rite_Aid_OMDL_0017426; Rite_Aid_OMDL_0017428; Rite_Aid_OMDL_0017435; Rite_Aid_OMDL_0017707; Rite_Aid_OMDL_0017830; Rite_Aid_OMDL_0018313; Rite_Aid_OMDL_0018314; Rite_Aid_OMDL_0018508; Rite_Aid_OMDL_0018510; Rite_Aid_OMDL_0018989; Rite_Aid_OMDL_0019015; Rite_Aid_OMDL_0019459; Rite_Aid_OMDL_0019623; Rite_Aid_OMDL_0019625; Rite_Aid_OMDL_0019824; Rite_Aid_OMDL_0019902; Rite_Aid_OMDL_0020274; Rite_Aid_OMDL_0021184; Rite_Aid_OMDL_0024889; Rite_Aid_OMDL_0025346; Rite_Aid_OMDL_0025356; Rite_Aid_OMDL_0038603; Rite_Aid_OMDL_0038610; Rite_Aid_OMDL_0038618; Rite_Aid_OMDL_0038620; Rite_Aid_OMDL_0038624; Rite_Aid_OMDL_0038672.

System (*see, e.g.*, Rite_Aid_OMDL_0015302 - Rite_Aid_OMDL_0015303; Rite_Aid_OMDL_0023658; Rite_Aid_OMDL_0036812 - Rite_Aid_OMDL_0036814), dispensing records in the form of Drug Utilization Reports ("DUR Reports") (*see, e.g.*, Rite_Aid_OMDL_0015304; Rite_Aid_OMDL_0023642; Rite_Aid_OMDL_0023659; Rite_Aid_OMDL_0036811), and in some cases Rite Aid Prescriber Activity Reports for the requesting pharmacy) and spoke to the Pharmacy District Manager to determine whether a threshold increase was warranted. Approvals for threshold increases were reviewed regularly to confirm that they were still warranted. No above-threshold orders were shipped to a Rite Aid Pharmacy unless the pharmacy had prior approval from the Government Affairs department at Rite Aid Hqtrs. Corp.

Rite Aid of Maryland showed DEA inspectors copies of its Threshold Log and policies and procedures during each DEA audit of the Perryman Distribution Center, including during a DEA audit in July 2012 when DEA inspectors specifically complimented Rite Aid of Maryland on its excessive order monitoring program. *See, e.g.*, Rite_Aid_OMDL_0012547.

In addition to the order monitoring at the Perryman Distribution Center described above, during the relevant period, Rite Aid Hqtrs. Corp. used an Auto Replenishment System ("ARS") to calculate and limit orders from Rite Aid Pharmacies. The ARS, through the use of algorithms, created a suggested order for each Rite Aid Pharmacy based on the particular pharmacy's [redacted] prior dispensing history and inventory (weighting the more recent weeks more heavily). *See, e.g.*, Rite_Aid_OMDL_0046321.

The suggested order for a pharmacy was pre-populated into a pharmacy's order to refill the pharmacy's needs. Pharmacists could "override" the ARS order, but only within certain limits. Pharmacists generally could not increase an order more than [redacted] above the highest order in the

last [redacted]. *See* Rite_Aid_OMDL_0046321. If the "override" amount was greater than the max-limit, then the ARS automatically blocked the "override" and capped the order at the max-limit. *See id*. In addition to the [redacted] limit, the ARS also imposed a [redacted]-bottle cutoff for any medication in any order absent a specific change at the corporate level to that [redacted]-bottle default cutoff (this is in addition to the 5,000 dosage unit per order threshold discussed above). *See id*.

In addition to the order monitoring at the Perryman Distribution Center and the controls on orders imposed through the ARS, described above, during the relevant time period, Rite Aid Hqtrs. Corp. employees in the Loss Prevention department analyzed various reports and data related to pharmacy orders. Rite Aid of Maryland produced documents related to reports, reviews, and analysis conducted by Loss Prevention personnel related to order monitoring (including those generated by the NaviScript and Access systems) and resulting investigations in the Track One jurisdictions. *See, e.g.*, Rite_Aid_OMDL_0044562 - Rite_Aid_OMDL_0044564; Rite_Aid_OMDL_0044734 - Rite_Aid_OMDL_0044736; Rite_Aid_OMDL_0037225 - Rite_Aid_OMDL_0037228; Rite_Aid_OMDL_0044221. For instance, during the relevant time period, Loss Prevention personnel reviewed and analyzed monthly Above Average Controlled Drug Purchases reports (formerly known as Above Average Controlled Drug Purchases Checklists) that compared, at the pharmacy level, the amount of controlled drugs purchased and dispensed.[6] *See, e.g.*, Rite_Aid_OMDL_0046228. In addition, Loss Prevention personnel reviewed a variety of "key performance indicators" relating to pharmacy orders for potential anomalies. *See, e.g.*, Rite_Aid_OMDL_0043464. If anomalies were identified, the Loss

[6] These reports were also available to Pharmacy District Managers during the relevant time period.

Prevention department would initiate an investigation and open a case in LPMS (formerly known as NaviCase and EthicsPoint).

INTERROGATORY NO. 7: Please Identify all industry associations or other organizations that provided education, information, services or had any involvement with the use, safety, efficacy, production, marketing, sale, dispensing or distribution of Opioid and/or Opioid Products that You are or were a member of, or to which You provided financial or other support, from 1990 to present. Additionally, identify what if any positions Your employees, officers, or directors have held with any such organizations from January 1, 1990 to present.

AMENDED ANSWER: Subject to and without waiving the foregoing objections and Rite Aid of Maryland's prior objections to this Interrogatory, Rite Aid of Maryland responds as follows:

Rite Aid of Maryland does not track, in the ordinary course, the outside organizations to which its employees belong. Based upon a reasonable investigation, Rite Aid Hqtrs. Corp. paid membership dues to the National Association of Chain Drug Stores ("NACDS") and the Maryland Association of Chain Drug Stores during the relevant time period. In addition, during the relevant time period, Janet Getzey Hart (Director, Government Affairs, Rite Aid Hqtrs. Corp.) regularly attended and participated in meetings with the following organizations: NACDS, the Maryland Association of Chain Drug Stores, the National Association of State Controlled Substances Administrators ("NASCSA"), and National Association of Boards of Pharmacy ("NABP"). Rite Aid of Maryland further responds that John Standley was elected as the chairman of NACDS in 2014. Rite Aid of Maryland also responds that it maintained a Verified-Accredited Wholesale Distributors ("VAWD") accreditation from NABP from 2007 through the time it stopped distributing controlled substances in October 2014.

INTERROGATORY NO. 8: Please Identify any Customer, including any Defendant in this case, to whom You provided (by sale or otherwise) data regarding the distribution and/or dispensing of Opioids or Opioid Products, and describe in detail the data You provided and the date that You provided the data. Plaintiffs limit this request to the state of Ohio from January 1, 1990 to present.

Exhibit F

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL NO. 2804
THIS DOCUMENT RELATES TO ALL CASES	:	CASE NO. 1:17-MD-2804
	:	Hon. Dan A. Polster

- - -

January 31, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of JANET GETZEY HART taken pursuant to notice, was held at the law offices of Morgan, Lewis & Bockius LLP, 1701 Market Street, Philadelphia, Pennsylvania, beginning at 9:38 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Registered Merit Reporter and Notary Public.

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need in the order.

Q. So when an order is going to be placed, the pharmacist has access to see what that order is?

MS. McENROE: Objection.

THE WITNESS: Yes. The pharmacist has to have access to see that order.

BY MR. PIFKO:

Q. So it's in this automated system, but then there's some screen where the pharmacist can see what the automated system is calculating for the order?

A. Yes.

Q. Is there a name for that screen?

A. I don't know what the name is.

Q. Is the pharmacist required to check the order before it's placed every time?

A. Typically they do. I don't know if it's required.

Q. And so orders are placed by Rite Aid stores with a regular frequency. Correct?

A. Orders are placed once a week, once every other week in a limited number of

stores, and twice a week in a very limited number of stores.

Q. So let me break that down.

So most -- what most -- what's the ordering pattern for most stores?

A. Most stores, Rite Aid places an order once a week.

Q. Some stores place two orders a week?

A. Some stores place two orders a week, yes.

Q. Some stores place orders every two weeks?

A. Yes.

Q. Is there any other ordering pattern that we haven't discussed?

A. No. The stores are -- once a store is programmed in, they can't place additional orders.

Q. Well, I'm just trying to understand. So there's three categories here.

There's stores that order once a week, which is most of the stores.

Then there's another category of

Exhibit G

To: Wilson A Lester Jr[wlester@riteaid.com]; kemitchell@riteaid.com[kemitchell@riteaid.com]
Cc: bgallagher@riteaid.com[bgallagher@riteaid.com]; Robert Sari[rsari@riteaid.com]; Mary F Sammons[msammons@riteaid.com]
From: Anthony J. Bellezza
Sent: 2005-09-22T23:42:11-04:00
Importance: Normal
Subject: RE: DEA Audit - Perryman Distribution Center
Received: 2005-09-22T23:42:00-04:00

Wilson and Kevin,

Thank you for keeping me posted on the DEA inspection.

Kevin, congratulations on a great job – we appreciate your efforts and the team at Perryman.

All the best,

Tony

From: Wilson A Lester Jr
Sent: Wednesday, September 21, 2005 2:17 PM
To: Anthony J. Bellezza
Cc: kemitchell@riteaid.com; Tim Peifley; rroberson@riteaid.com
Subject: FW: DEA Audit - Perryman Distribution Center

Tony, I wanted to apprise you of the "clean slate" that we received from the DEA' s recent audit of our Perryman DC. As you are aware, Perryman serves some 2139 of Rite Aid's 3350 pharmacies. Our favorable results can be directly attributable to the strong compliance leadership and high professional standards fostered by Kevin Mitchell and the ownership, pride, and flawless day in and day out execution of the Perryman Pharmacy Operations Team.

Wilson

From: Kevin E. Mitchell [mailto:kemitchell@riteaid.com]
Sent: Wednesday, September 21, 2005 2:02 PM
To: Wilson A Lester Jr
Cc: Robby Roberson; 'Tim Peifley'
Subject: DEA Audit - Perryman Distribution Center

Wilson,

The investigator's from the DEA office in Baltimore have departed from Perryman with very positive comments regarding our Pharmacy Operation.

The audit was conducted from Monday, September 19 through Wednesday, September 21. They were very impressed with the level of detail and ownership that the staff in Perryman has with controlled substances.

The DEA focused primarily on 3 areas:

1) Accountability – All 8 items selected balanced to zero which means that our inventories were exactly on (Time period 9/19/04 – 9/20/05)

2) Security – Checked all alarms, camera's, processes as it relates to drug security

3) Record Keeping –

a. Distribution records

b. Receiving records

c. Biennial inventory

d. Verification of all procedures

The closing comments mentioned specifically that they have no words of advice for the Staff for improvement. It was a flawless audit.

A special thanks goes out to Debra Chase (DEA Coordinator), Marian Wood (Pharmacy Manager) and Keith Frost (Pharmacy OPS Mgr). These are the people that made these results happen.

Kevin

Kevin E. Mitchell
Sr Manager, Regulatory Compliance
Six Sigma Blackbelt
Rite-Aid Corporate Office
30 Hunter Lane
Camp Hill, PA 17011
(717) 214-8815
(717) 975-5942 fax
kemitchell@riteaid.com

To: Marian L. Wood[mwood@riteaid.com]; Debra Chase[dchase@riteaid.com]
Cc: 'Darla Harkins'[dharkins@riteaid.com]; Marcie Bolling[mbolling@riteaid.com]; 'Tahir Senoussi'[tsenoussi@riteaid.com]; 'Rita Custer'[rcuster@riteaid.com]
From: Kim Brown
Sent: 2009-09-30T14:32:46-04:00
Importance: Normal
Subject: FW: DEA Audit
Received: 2009-09-30T14:32:52-04:00

Great job everyone!
We do need to remain DEA compliant and make sound decisions throughout our process. Like Tim states below... "It's not likely we'll go four years again without a visit". Kudos to Marian for having everything PERFECT!!!

Kimberly Brown
Rite Aid Corporation
Pharmacy Dept Mgr
410-297-6069 / 5156

From: Tim Peifley [mailto:tpeifley@riteaid.com]
Sent: Wednesday, September 30, 2009 2:22 PM
To: KEmitchell@riteaid.com; Robert Shovel
Cc: Tim Peifley; wmorrow@riteaid.com; 'Kim Brown'; Joyce E Sweitzer
Subject: DEA Audit

The DEA auditors returned today (9/30) to complete their audit. Today they concentrated on security and they walked the cage area and tested the alarms. We sat down afterwards for a wrap-up and here are some notes/highlights:

- They said they normally concentrate on two things, (1) Security and (2) Recordkeeping.
- He said security was "excellent." Having 30-60 days of video back-up is a plus.
- The only recommendation they are going to make for the entire audit is to add a camera directly over the area where we receive and break down the cage receipts. We have camera coverage of the area but he thought it would be beneficial to have one direclty overhead. We have money in the capital budget for a second phase of the camera project so we should be able to include this in that scope.
- He asked some questions about the alarm system, specifically about the back-up to the system if the main line gets cut. We owe him some information on this. He wanted to see the contract and how it described the back-up system, how long it was good for... We will fax it to him once we get the contract language.
- As for recordkeeping, they counted five controlled items and all five balanced out perfectly. He stated that the frequent wall-to-wall inventories were great and he was thankful that we document and print out a specific biennial inventory, even though we do much more than that basic requirement. He said that as many as 80% of the sites they inspect do NOT do this for

them.

- I asked him what he thought about our 106 activity since it was an area of concern with our state guy who visited a few months ago. He said he had reviewed them and he feels good about it. Most of the incidents are due to vendor shortage, not internal losses.
- They asked for store information and we expect them to visit some Baltimore area stores in the near future. They took location information for 11 Baltimore stores and 2 Anne Arundel County stores. I have notified the regional management in charge of those areas of the store numbers they took with them so they can prepare those stores for potential DEA visits. I also gave them the SKU's that were counted here since they were chosen due to recent street activity and it is likely they'll count some or all of the same items.
- The inspectors stated that there will be a lot more audits in the Baltimore area ("ten-fold") so we could expect to see them more frequently. It's not likely we'll go four years again without a visit. They did say this was a Baltimore-specific initiative, not a nationwide one.
- There will be no official report as a result of this visit. There will be no Memorandums of Understanding as a result of the audit. He stated, "Everything we saw meets the requirements of what we came to see. I'm happy, very happy."

Thanks to everyone who made this an exceptionally successful audit of an immensely critical part of our operation and the Supply Chain's overall mission as well.

Tim

To: Anna Karn[akarn@riteaid.com]; Anna Anders[aanders@riteaid.com]; Marcie Bolling[mbolling@riteaid.com]; Marian L. Wood[mwood@riteaid.com]; Debra Chase[dchase@riteaid.com]; Rebecca Strickland[Rebecca.Strickland@riteaid.com]; Linda Stewart[Linda.Stewart@riteaid.com]
Cc: Keith Frost[kfrost@riteaid.com]
From: Keith Frost
Sent: 2012-07-11T15:26:21-04:00
Importance: Normal
Subject: Please review 'DEA Audit July 11'
Received: 2012-07-11T15:26:22-04:00
DEA Audit July 11.doc

Great job everyone for making this audit very successful. Please share with our associates.

Keith

July 11, 2012

I. DC10 DEA Audit Results: No findings or discrepancies-100% accountability.

II. Summary of audit:

1. Two inspectors from the DEA arrived yesterday at approximately 10:40 am to conduct an unannounced audit.
2. On Tuesday they asked for and received-Org chart, info on Medturn our reverse distributor, which company does our drug testing, which company handles our alarm security, etc.
3. On Tuesday we also conducted a physical count of 8 CD items in both the FP and Storage location (100% correct). Today the audits did an accountability of a whole years worth of receipts, distribution (movement) and adjustments of these same 8 items (period 2 July, 2011 through 10 July, 2012). The results were a 100% accountability.
4. Today the DEA inspectors arrived at 10:20 am and continued looking at:
    a. Information of all managers and leads assigned and having access to the CD cage, information included DOB, address, SSN, and fullname.
    b. Building floor plan and control cage floor plan showing motion sensors.
    c. Conducted a Cage alarm motion test for vault and entire cage between us and Checkpoint.
    d. Asked for information of CD% to sales of all RX.
    e. Provided copies of all state and DC licenses, as well as a copy of VAWD certificate.
    f. List of CD vendors and their addresses.
    g. File of thefts and losses (106's) from July 1, 2011 to July 10, 2012.
    h. Looked at and received a copy of Biennial and Annual full inventory results.
    i. Date company was incorporated and list of company officers.
    j. Went to Asset Protection camera monitoring room to observe locations of all DC cameras. Including outside building cameras.
    k. Provided a copy of CD picklist and receipt P.O.
    l. Provided a list of all Rite Aid DCs.
    m. Observed associates picking in cage.
    n. Observed associates using new Quality Assurance (QA) stations to verify all CD picks. They liked the fact that we are using technology to reduce human error.

III. Shout out: Both DEA inspectors are very impressed and pleased to see that Rite Aid demonstrates its due diligence by having an excellent excessive order monitoring program. They mentioned that the DEA is taking a harder look at all distributors to ensure that order monitoring processes are in place and effective.

IV. Asked if our stores had Drug Take Back program and that they are pushing this nationwide in communities to reduce expired and excessive drugs on the street.

Exhibit H

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
	:	MDL NO. 2804
APPLIES TO ALL CASES	:	
	:	CASE NO. 17-MD-2804
	:	

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VOLUME I

- - -

May 16, 2019

- - -

Videotaped deposition of DR. SETH B. WHITELAW, taken pursuant to notice, was held at the offices of Golkow Litigation Services, One Liberty Place, 1650 Market Street, Philadelphia, Pennsylvania beginning at 9:18 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

new developments that are relevant to the work that I've already done, so...

BY MR. EPPICH:

Q. But these reports express -- represent your complete set of opinions in this case; is that true?

A. At this moment in time, as you'll notice in my original report, I reserve the right to supplement the report should new and additional information come to light that's relevant to the work that I've done.

Q. Do you have any changes to make to either of your reports sitting here today?

A. Not that I can think of.

Q. You still hold all of the opinions expressed in these reports?

A. Yes, sir, I do.

Q. In writing your report, did you report -- did you write the first draft of your report?

A. Chris, I wrote every draft

Exhibit I

STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, Secretary

Division of Drug Control
4201 Patterson Avenue
Baltimore, Maryland 21215
410-764-2890

Controlled Dangerous Substances (CDS)
Establishment Inspection Report

1. PERMITS AND LICENSES:

Establishment Classification Distribution
Establishment Name Rite Aid Mid-Atlantic Customer Center
Address 601 Chelsea Rd City Aberdeen Zip 21001
Telephone 410-297-6334 Fax. 410-297-6049 County: Harford CO
Establishment Registration/Permit Number D01005 Expiration 12-31-2012
Maryland CDS Registration Number 244950 Expiration 10-31-2013
DEA Registration Number [redacted] Expiration 4-30-2013
DEA Registrant General Manager
Establishment Hours of Operation: M-F 7-5 Sat. 7-5 Sun. C Hol.
Inspection Date 8-21-2012 Arrival Time 11:00 Departure Time 1:45

2. PERSONNEL:

Personnel on duty	License No. (if applicable)	Expiration Date
Marian Wood. DEA Coordinator		

3. RECORD KEEPING REQUIREMENTS:

No scheduled II drugs ordered.

Yes	No		
☐	☐	a.	Is the paper DEA Form 222 utilized?
☐	☐	b.	If yes to the above, are DEA Form 222s maintained separately from other records and kept available for 2 years? (21 CFR 1305.17)
☐	☐	c.	Are powers of attorney authorizing individuals to order Schedule II drugs on file? (21CFR 1305.05)

NA

Yes No

NA

- ☐ ☐ d. Are DEA Form 222 orders signed and dated by registrant or a person authorized by a power of attorney? (21 CFR 1305.05)
- ☐ ☐ e. Does the purchaser record, for each line item on DEA Form 222, the quantity received and the date received? (21 CFR 1305.13(e))
- ☐ ☐ f. Are Schedule II products ordered using CSOS (controlled substance ordering system)?
- ☐ ☐ g. If yes to above, when an order is received, is a record created of the quantity of each item received and the date received, and is this record electronically linked to the original order and archived? (21 CFR 1305.22 (g))
- ☐ ☒ h. Are CDS provided to the establishment by a pharmacy?
  If so, name of pharmacy _____
- ☐ NA i. If yes to above, are these transactions done using a DEA Form 222 for Schedule II products or a purchase order for Schedule III – V products? (21 CFR 1307.11)
- ☑ ☐ j. Are receipts and invoices for Schedule III – V CDS being dated upon receipt? (21 CFR 1304.21)
- ☑ ☐ k. Is the Biennial Inventory of CDS being taken and maintained as required? (COMAR 10.19.03.05 B)
  Date 5-1-2012 (Open)/ Close of business By whom Marian Wood.
- ☐ NA l. Are Schedule II CDS surrendered for disposal done using DEA Form 222?
  If yes, name of reverse distributor used ~~Mariar~~ n/a
- ☐ NA m. Are transfers of Schedule II CDS made between establishments?
- ☐ NA n. If yes, is a DEA-222 form used when transfers are made? (21 CFR 1305.03)

4. SECURITY CONTROLS AND CDS LOSS REPORTING:

Yes No

- ☑ ☐ a. Does the establishment use a perpetual inventory system for Schedule ~~II~~ III-V CDS?
  How often is it verified? Weekly By whom? Scheduled Personnel.
- ☑ ☐ b. If yes to the above, is there a policy for reconciliation of any difference in the perpetual inventory count and the actual count of Schedule ~~II~~ III-V CDS?
  Who reviews any discrepancy found? Marian Wood.
- ☑ ☐ c. Is any significant loss of any CDS, upon discovery of such a loss or theft, reported to the regional office of the DEA and the Division of Drug Control (DDC) using DEA Form 106? (COMAR 10.19.03.12B(4))
  Who makes the decision on what is significant? Marian Wood.
- ☑ ☐ d. Does the establishment provide effective controls and procedures to guard against theft and unlawful diversion of CDS? (COMAR 10.19.03.12A(1))

  ☑ Background checks ☑ Drug testing ☑ Alarms ☑ Video cameras ☑ Access to CDS limited through electronic badge
- ☑ ☐ e. Are all CDS stored in a securely locked, substantially constructed cabinet? (COMAR 10.19.03.12 B(1-2))
- ☑ ☐ f. Is the registrant or designee always immediately available on the premises to provide services at all times that the establishment is in operation?

5. CDS DISPOSITION RECORDS:

6. INVENTORY OF SCHEDULE II PRODUCTS: as of _____

Drug Name/Strength/Form	Count	Perpetual Inventory
1. No Schedule II. drugs		
2. on premises.		
3.		
4.		

Count performed by: _____

Counts do / do not include CII orders received on _____

7. INSPECTION SUMMARY:

Inspector comments and recommendations:
The facility has a good system for receipt and accountability of CDS. All significant loss of CDS upon receipt of shipment are promptly reported and follow up action with the vendors are documented.

Actions required by this report:
None.

8. REQUIRED ACTION DATE AND REPORT SIGNATURES:

Date required action must be completed: -

Name of registrant or designee: MARIAN WOOD
(print)

Signature of registrant or designee: Marian Wood

Inspector: CHANDRA K. MOULI
(print)

Signature: Chandra K Mouli

Notes from visit by Deputy Chief from the Maryland Division of Drug Control, Chandra K. Mouli, R. Ph. On Wednesday February 4, 2009:

Mr. Mouli arrived at the Perryman facility around 11:30AM on the 4th. He was taken to Training room 1 for a meeting. Present from Rite Aid were Tim Peifley (GM), Joyce Sweitzer (LP), Bill Morrow (Senior Operations Manager), Kim Brown (Rx Department Manager), and Marian Wood (DEA Coordinator.)

Mr. Mouli asked several questions, all of which are included in the attached checklist. After finishing the checklist he moved on to what appeared to be the real reason for his visit, the frequency of the Form 106's filed out of the Perryman DC. He says he was concerned about the amount of 106's coming from us. He had a file containing all 106's going back to (the State's) Fiscal 2002. The list of 106's filed during calendar 2007 and 2008 is attached.

We focused our discussion on two different types of incidents. First, when a shipment comes to us from a vendor and we discover a shortage, we file a 106 as required. At first Mr. Mouli seemed to be pushing us to do more than just report it. He asked what else we do, and we told him that the buyers in corporate often get involved and they call the vendor or even Fed Ex. He stated that even though the proper forms are filed, he is still concerned because the drugs are "out on the street somewhere." We told him that the vendor is not likely to disclose to us what their findings are and he then stated that, "Your responsibility pretty much ends once you file the 106." He did ask us to call him if we ever see a shortage of 12 or more units on a shipment and he said he would come in and call the vendor himself and seek answers. His only recommendation in this area was for us to include the tracking # on the 106 where we state the carrier's name.

We then discussed the shortages that we file when our inventory does not reconcile. We only had 17 of these in all of 2008 out of a total of 39 106's filed. I told him that we fill over 7 million units of controlled drugs a year, and he said that we were "very large." We never confirmed what he thought was an acceptable level of 106's coming from an operation this large. He did acknowledge that all of our shortages were for 1 or 2 bottles, but some of them are desirable "street drugs" and they raise flags if they are missing. We told him that we inventory our forward picks at the end of each shift and if we have a confirmed shortage we notify all stores picked that day to check their order in closely and let us know if they get an item they aren't supposed to or if they have an overage on the item in question. He asked why in these cases we did not hear back from the stores. We told him we normally only hear back if someone finds it. He was very concerned that a store could get an overage and not report it. He mentioned several times that we should demand more from stores when we have a shortage. First, we should require every store that is sent the Sysm to respond, even if it's a negative response. Second, we should notify them that as registered licensees of the Board of Pharmacy they are accountable for what they sign for, and if there is an overage in the shipment they are required to report it.

He even suggested that we "plant" an overage in a store and see if they report it. We are not in favor of that and do not plan to take that approach.

The following items were requested for review by Mr. Mouli:

- DEA license
- MD Controlled Substance license
- Maryland Board of Pharmacy license
- Receiving procedures
- Number of all 106's filed during calendar 2007 and 2008
- Controlled Drug Cage Access List
- Bi-annual inventory information and results
- Procedures on investigating inventory shortages

Mr. Mouli took copies with him of the following items:

- DEA license
- Maryland Controlled Substance License
- Receiving procedures

We still owe him the following. They will be sent to him by February 10th:

- Number of all 106's filed during calendar 2007 and 2008
- Procedures on investigating inventory shortages

Summary: As you can see on the actual report (attached) the only action item required as a result of the visit was to include tracking number or pro number along with the carrier information when we report a vendor shortage. We do not feel that he was overly concerned about the level of 106 activity he sees out of this facility, but we believe that if it spikes even slightly that he will return or call immediately for more information. We would recommend that the stores in the State of Maryland be advised that the level of audit activity will pick up this year since Mr. Mouli stated that they have gotten more resources and that he is very concerned about 106 volumes and how stores handle overages and shortage.

Exhibit J

STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue? Baltimore, Maryland 21215-2299
Michael Souranis, Board President - LaVerne G. Naesea, Executive Director

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS AND DEVICES INSPECTION REPORT

Permit: D01005
Inspection Result
Type of Inspection Annual

Inspection Date 8/16/2012
Previous Insp. Date: 8/26/2010
Inspector ShanelleY

Distributor DBA Name RITE AID MID ATLANTIC
Address 601 CHELSEA ROAD
Corporate Distributor Name
City ABERDEEN **State** MD **Zip** 21001430
Telephone 410-297-6000
Fax 410-297-6001
Permit Exp. Date 2012

License, Registration or Permit numbers issued by another state or federal authority
SEE ATTACHED

CDS Registration # 244950 **CDS Exp. Date** 10/31/2013 **DEA #** [redacted] **DEA Exp. Dat** 4/30/2013

States of Licensure SEE ATTACH

I time 10:30am **Departure Time** 12:30pm
of Operation M - F 7PM-5PM **Saturday** 6:30AM-5PM **Sunday** 7PM-5PM

Comments OK.

2. PERSONNEL (COMAR 10.34.22.02)

Name of Designated Representative who is the primary contact of the wholesale distributor with the Board and is actively involved in, and aware of, the daily operation of the wholesale distributor. COMAR 10.34.22.02(8)
KEITH FROST, PHARMACY MANAGER

Yes The Designated Representative is physically present, except for an authorized absence, at the facility of the wholesale distributor during regular business hours. COMAR 10.34.22.03D (3)

Yes The Designated Representative is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D (3)

Name of Immediate Supervisor of the Designated Representative
JOHN COOPER, DM

Yes The Immediate Supervisor is actively involved in, and aware of, the daily operations of the wholesale distributor. COMAR 10.34.22.03D (4)

Yes The Immediate Supervisor is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D(4)

Yes The wholesale distributor maintains a list of responsible individuals (officers, directors, managers, the designated representative, and others in charge if wholesale distribution, storage, and handling). The list includes: (attach list) COMAR 10.34.22.07C

Yes The description of the duties of the responsible parties
Yes A summary of the qualifications of the responsible parties

Comments OK.

3. PERSONNEL TRAINING

Yes All personnel employed in wholesale distribution have documented education and experience to assume the corresponding responsibilities. COMAR 10.34.22.04A

The Designated Representative:

Ye Is aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, including applicable State and federal laws. COMAR 10.34.22.04C(1)

Y | Has had documented education sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws COMAR 10.34.22.04C(2); and

Yes Has received this education provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations. COMAR 10.34.22.04C(2).

Yes Maintains current working knowledge of the requirements for wholesale distributors. COMAR 10.34.22.04C(3)

Yes Assures an ongoing training program for personnel to ensure compliance with applicable State and federal laws. COMAR 10.34.22.04C(3)

Yes Maintains all personnel training records and makes all records available for inspection. COMAR 10.34.22.04C(4)

Comments OK. TRAINING SENT FROM CORPORATE OFFICE.

4. STORAGE AND HANDLING OF PRESCRIPTION DRUG AND DEVICE

The facilities at which the prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed COMAR 10.34.22.06A:

Yes Is of suitable size and construction to facilitate appropriate cleaning, maintenance and proper operation.

Yes Is maintained in a clean and orderly manner

Yes Is free from infestation by insects, rodents, birds, or vermin.

Yes The prescription drugs or devices storage area is equipped with:

- Yes Proper Equipment
- Yes Humidity Control
- Yes Adequate Lighting
- Yes Appropriate Sanitation
- Yes Sufficient Space
- Yes Appropriate Temperature
- Yes Appropriate Ventilation

Y The prescription drug or devices storage area is maintained at the appropriate temperature as established by labeling of the drug or device; or set forth in an official compendium; or at a controlled temperature that ensures identity, strength, quality and purity of the drug or devices are maintained. COMAR 10.34.22.06C

Yes The facility uses appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices. COMAR 10.34.22.06C(3)

The wholesale distributor, upon receipt of a prescription drug or device, visually examines each outside shipping container to: COMAR 10.34.22.06D(1)

- Yes Assure identity
- Yes To prevent the acceptance of prescription drugs or devices that are contaminated or therwise unfit for distribution

Yes The visual examination performed upon receipt of a prescription drug or device is adequate to reveal container damage that would suggest possible contamination or other damage to the contents. COMAR 10.34.22.06D(2)

The wholesale distributor carefully inspects each outgoing shipment to: COMAR 10.34.22.06D(2)

- Yes Assure the identity of the prescription drug or device product
- Yes To ensure there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions

Yes The wholesaler distributor maintains records of the examination of incoming and outgoing prescription drug and device products. COMAR 10.34.22.06D(4)

Yes The wholesale distributor identifies, marks or has a quarantine area that physically separates prescription drugs and devices that are adulterated, damaged deteriorated, misbranded, outdated or in immediate or sealed secondary containers that have been opened from other prescription drugs and devices. COMAR 10.34.22.06E

Comments OK. REVIEWED TEMP LOGS AND QUARANTINE AREA.

5. SECURITY COMAR 10.34.22.06B

The facility is designed to prevent unauthorized entry through:

Yes Controlled access from outside the premises

Yes The outside perimeter of the premises is well lit.

Ye The entry into areas where prescription drugs and devices are held are limited to authorized personnel

The facility is equipped with:

[ ] An alarm system to detect entry after hours.

[Yes] A security system that provides protection against theft and diversion.

[Yes] A security system to protect the integrity and confidentiality of data and documents.

[Yes] A video monitoring system for all entrances and exits, or alternate acceptable security.

[Yes] Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records.

[Yes] An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting.

[Yes] An ongoing security data and documentation retention program which is readily available to the Board, an agent of the Board, or federal and other State law enforcement officials.

Comments: OK.

6. PRESCRIPTION DRUG OR DEVICE DISTRIBUTION RECORDS COMAR 10.34.22.

[Yes] The wholesale distributor maintains, for up to 3 years from the date of their creation, inventories and records of transactions regarding the receipt and distribution or disposition of prescription drugs and devices

The documentation of inventory and records of transactions include:

[Yes] The source of the prescription drugs and devices

[Yes] The name and principal address of the seller or transferor

[Yes] The address of the location from which the prescription drugs or devices were shipped

[Yes] The identity and quantity of the prescription drugs and devices received and distributed or disposed of

[Yes] The dates of receipt and distribution or other disposition of the prescription drugs or devices

[Yes] The pedigrees, if required by Health Occupations Article §12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

[Yes] The wholesale distributor makes records readily available for review at the inspection site, by computer or other means. If no:

[ ] The wholesale distributor makes available within 5 business days of the request, records kept at a central location apart from the inspection site and not electronically retrievable

[Yes] The wholesale distributor has established and maintains procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting to the Board and the FDA.

[Yes] The wholesale distributor maintains a system and records for the mandatory reporting to the Board, the FDA and where applicable the DEA, significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring or has occurred.

The wholesale distributor has established, maintained, and adheres to written policies and procedures for:

[Yes] the receipt, security, storage, inventory and distribution of prescription drugs or devices

[Yes] identifying, recording and reporting losses or thefts

[Yes] correcting errors and inaccuracies in inventories

The wholesale distributor has included in the written policy and procedure:

[Yes] A procedure by which the oldest approved and unexpired stock of a prescription drug and device is distributed first

[Yes] Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device

Y A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility in the event of a strike, fire, flood, catastrophic health emergency, terrorist activities, other natural disaster or other situations of local, State or national emergency

Yes A procedure to ensure that an outdated prescription drug and device is segregated from other drugs or devices and either returned to the manufacturer or destroyed.

Yes The wholesale distributor maintains documentation of the disposition of outdated prescription drugs or devices for up to 2 years after the disposition of the outdated prescription drugs and devices.

N/A A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, which includes:

- N/A all necessary documentation, maintained for a minimum of 3 years
- N/A the appropriate witnessing of the destruction of any labels, packaging, immediate containers in accordance with applicable State and federal laws

Yes A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, and suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

N/A If the wholesale distributor performs prescription drug product salvaging and reprocessing, policies and procedures are in place to perform due diligence on transactions.

N/A If the wholesale distributor performs prescription device product salvaging or reprocessing, policies and procedures are in place to perform due diligence on transactions.

Comments: OK.

7.DUE DILIGENCE COMAR 10.34.22.07

No The wholesale distributor has had transactions with persons not licensed by the Board or not certified by a third party recognized by the Board. If yes, the wholesale distributor has policies and procedures to ensure:

- N/A Verification of alternate licensure
- N/A Verification of identity
- N/A Verification of recent inspections by a state or third party entity recognized by the Board

Comments: NONE

Inspector Comments: REVIEWED INSPECTION FORM WITH MARIAN L. WOOD, DEA COORDINATOR & KEITH FROST, PHARMACY DAY DEPARTMENT MANAGER/DESIGNATED REP . THIS FACILITY DISTRIBUTES PHARMACEUTICALS INCLUDING CDS TO RITE AID PHARMACIES. PLEASE NOTE THIS FACILITY IS VAWD ACCREDITED. REVIEWED TRAINING DOCUMENTATION, TEMP LOGS, INVOICES, AND WRITTEN POLICIES/PROCEDURES. ALL DOCUMENTS NEEDED FOR THIS INSPECTION WERE EASILY RETRIEVED.

Designated Representative Name: KEITH FROST Date: 8/16/2012

Pharmacist Signature:

Inspector Signature: Shanlee Young

STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue• Baltimore, Maryland 21215-2299

Michael N. Souranis, Board President - LaVerne G. Naesea, Executive Director

WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS AND DEVICES INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Wholesale Distributor Name Rite Aid Mid Atlantic
Wholesale Distributor Name-Doing Business As (d/b/a) or Trade Name _____

Street Address 601 Chelsea Rd. Aberdeen, MD. 21001
Business Telephone Number 410-297-6000 **Business Fax Number** 410-297-6001
Maryland Permit Number D01005 **Expiration** 12-31-10
License, Registration or Permit numbers issued by another state or federal authority

CDS Registration Number 244950 **Expiration** 10-2011
DEA Registration Number [redacted] **Expiration** 12-31-10
States of Licensure See Attached
Hours of Operation: Mon-Fri 630am - 430
Inspection Date: 8-26-10 **Arrival Time:** _____ **Departure Time:** _____
Type of Inspection: ~~Annual~~ **Follow-up** **Previous Date:** _____
Name of Inspector: Jeannelle McKnight CPhT

2. PERSONNEL (COMAR 10.34.22.02)

Name of Designated Representative who is the primary contact of the wholesale distributor with the Board and is actively involved in, and aware of, the daily operation of the wholesale distributor. COMAR 10.34.22.02(8)
Tim Peifley

Yes No

☑ ☐ The Designated Representative is physically present, except for an authorized absence, at the facility of the wholesale distributor during regular business hours. COMAR 10.34.22.03D (3)

☑ ☐ The Designated Representative is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D (3)

Name of Immediate Supervisor of the Designated Representative Rob Shovlin

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DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258
Web Site: www.mdbop.org

Yes No

☑☐ The Immediate Supervisor is actively involved in, and aware of, the daily operations of the wholesale distributor. COMAR 10.34.22.03D (4)

☑☐ The Immediate Supervisor is a full time management level employee of the wholesale distributor. COMAR 10.34.22.03D(4)

☑☐ The wholesale distributor maintains a list of responsible individuals (officers, directors, managers, the designated representative, and others in charge if wholesale distribution, storage, and handling). The list includes: (attach list) COMAR 10.34.22.07C

Yes No

☑☐ The description of the duties of the responsible parties

☑☐ A summary of the qualifications of the responsible parties

3. PERSONNEL TRAINING

Yes No

☑☐ All personnel employed in wholesale distribution have documented education and experience to assume the corresponding responsibilities. COMAR 10.34.22.04A

The Designated Representative:

Yes No

☑☐ Is aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, including applicable State and federal laws. COMAR 10.34.22.04C(1)

☑☐ Has had documented education sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws COMAR 10.34.22.04C(2); and

☑☐ Has received this education provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations. COMAR 10.34.22.04C(2).

☑☐ Maintains current working knowledge of the requirements for wholesale distributors. COMAR 10.34.22.04C(3)

☑☐ Assures an ongoing training program for personnel to ensure compliance with applicable State and federal laws. COMAR 10.34.22.04C(3)

☑☐ Maintains all personnel training records and makes all records available for inspection. COMAR 10.34.22.04C(4)

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4. STORAGE AND HANDLING OF PRESCRIPTION DRUG AND DEVICES

The facilities at which the prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed COMAR 10.34.22.06A:

Yes No

☑☐ Is of suitable size and construction to facilitate appropriate cleaning, maintenance and proper operation.

☑☐ Is maintained in a clean and orderly manner

☑☐ Is free from infestation by insects, rodents, birds, or vermin.

☑☐ The prescription drugs or devices storage area is equipped with:

Yes No

☑☐ Proper Equipment

☑☐ Humidity Control

☑☐ Adequate Lighting

☑☐ Appropriate Sanitation

☑☐ Sufficient Space

☑☐ Appropriate Temperature

☑☐ Appropriate Ventilation

Yes No

☑☐ The prescription drug or devices storage area is maintained at the appropriate temperature as established by labeling of the drug or device; or set forth in an official compendium; or at a controlled temperature that ensures identity, strength, quality and purity of the drug or devices are maintained. COMAR 10.34.22.06C

☑☐ The facility uses appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices. COMAR 10.34.22.06C(3)

The wholesale distributor, upon receipt of a prescription drug or device, visually examines each outside shipping container to: COMAR 10.34.22.06D(1)

Yes No

☑☐ Assure identity

☑☐ To prevent the acceptance of prescription drugs or devices that are contaminated or therwise unfit for distribution

☑☐ The visual examination performed upon receipt of a prescription drug or device is adequate to reveal container damage that would suggest possible contamination or other damage to the contents. COMAR 10.34.22.06D(2)

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The wholesale distributor carefully inspects each outgoing shipment to: COMAR 10.34.22.06D(2)

Yes No

☑☐ Assure the identity of the prescription drug or device product

☑☐ To ensure there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions

Yes No

☑☐ The wholesaler distributor maintains records of the examination of incoming and outgoing prescription drug and device products. COMAR 10.34.22.06D(4)

☑☐ The wholesale distributor identifies, marks or has a quarantine area that physically separates prescription drugs and devices that are adulterated, damaged deteriorated, misbranded, outdated or in immediate or sealed secondary containers that have been opened from other prescription drugs and devices. COMAR 10.34.22.06E

5. SECURITY COMAR 10.34.22.06B

The facility is designed to prevent unauthorized entry through:

Yes No

☑☐ Controlled access from outside the premises

☑☐ The outside perimeter of the premises is well lit.

☑☐ The entry into areas where prescription drugs and devices are held are limited to authorized personnel

The facility is equipped with:

Yes No

☑☐ An alarm system to detect entry after hours.

☑☐ A security system that provides protection against theft and diversion.

☑☐ A security system to protect the integrity and confidentiality of data and documents.

☑☐ A video monitoring system for all entrances and exits, or alternate acceptable security.

☑☐ Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records.

☑☐ An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting.

☑☐ An ongoing security data and documentation retention program which is readily available to the Board, an agent of the Board, or federal and other State law enforcement officials.

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6. PRESCRIPTION DRUG OR DEVICE DISTRIBUTION RECORDS COMAR 10.34.22.07

Yes No

☑☐ The wholesale distributor maintains, for up to 3 years from the date of their creation, inventories and records of transactions regarding the receipt and distribution or disposition of prescription drugs and devices

The documentation of inventory and records of transactions include:
Yes No

☑☐ The source of the prescription drugs and devices

☑☐ The name and principal address of the seller or transferor

☑☐ The address of the location from which the prescription drugs or devices were shipped

☑☐ The identity and quantity of the prescription drugs and devices received and distributed or disposed of

☑☐ The dates of receipt and distribution or other disposition of the prescription drugs or devices

☑☐ The pedigrees, if required by Health Occupations Article §12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

☑☐ The wholesale distributor makes records readily available for review at the inspection site, by computer or other means. If no:
Yes No

☐☐ The wholesale distributor makes available within 5 business days of the request, records kept at a central location apart from the inspection site and not electronically retrievable

☑☐ The wholesale distributor has established and maintains procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting to the Board and the FDA.

☑☐ The wholesale distributor maintains a system and records for the mandatory reporting to the Board, the FDA and where applicable the DEA, significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring or has occurred.

The wholesale distributor has established, maintained, and adheres to written policies and procedures for:
Yes No

☑☐ the receipt, security, storage, inventory and distribution of prescription drugs or devices

☑☐ identifying, recording and reporting losses or thefts

☑☐ correcting errors and inaccuracies in inventories

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The wholesale distributor has included in the written policy and procedure:

Yes No

☑ ☐ A procedure by which the oldest approved and unexpired stock of a prescription drug and device is distributed first

☑ ☐ Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device

Yes No

☑ ☐ A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility in the event of a strike, fire, flood, catastrophic health emergency, terrorist activities, other natural disaster or other situations of local, State or national emergency

☑ ☐ A procedure to ensure that an outdated prescription drug and device is segregated from other drugs or devices and either returned to the manufacturer or destroyed.

☑ ☐ The wholesale distributor maintains documentation of the disposition of outdated prescription drugs or devices for up to 2 years after the disposition of the outdated prescription drugs and devices.

☑ ☐ A procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging cannot be used in counterfeiting activities, which includes:

Yes No

☐ ☐ all necessary documentation, maintained for a minimum of 3 years

☐ ☐ the appropriate witnessing of the destruction of any labels, packaging, immediate containers in accordance with applicable State and federal laws

Yes No

☑ ☐ A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, and suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

Yes No N/A

☐ ☐ ☑ If the wholesale distributor performs prescription drug product salvaging and reprocessing, policies and procedures are in place to perform due diligence on transactions.

☐ ☐ ☑ If the wholesale distributor performs prescription device product salvaging or reprocessing, policies and procedures are in place to perform due diligence on transactions.

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7. **DUE DILIGENCE** COMAR 10.34.22.07

Yes No

☐☑ The wholesale distributor has had transactions with persons not licensed by the Board or not certified by a third party recognized by the Board. If yes, the wholesale distributor has policies and procedures to ensure:

Yes No

☐☐ Verification of alternate licensure

☐☐ Verification of identity

☐☐ Verification of recent inspections by a state or third party entity recognized by the Board

INSPECTOR'S COMMENTS:

Facility ships only to its Rite Aid stores.
5. Facility has alarm systems as well as security on site 24/7. All exits/entrances have video monitoring including docks.

Facility is VAWD accredited.

Inspector Signature Jeanuella McKnight CPhT

Designated Representative Name: (Print) TIMOTHY J. PEIFLEY

Date: 8-26-10

Designated Representative Signature:

FINAL 12/17/08

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Chandra K Mouli R.Ph.
D.D.C.
Deputy Chief

STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

Division of Drug Control

Controlled Dangerous Substances (CDS) Inspection Report

1. PERMITS AND LICENSES

Distributor
~~Pharmacy~~ Name Rite Aid Midatlantic Customer Support Center, Perryman
Address 601 Chelsea Road Maryland 21130
Telephone 410-247-6000 Fax. 410-247-6003 County: Harford County
Maryland ~~Pharmacy~~ Permit Number _____ Expiration _____
Maryland CDS Registration Number 244950 Expiration 10-31-09
DEA Registration Number [redacted] Expiration 4-30-09
Pharmacy Hours of Operation: M-F 24hrs Sat. _____ Sun. _____ Hol. _____
Inspection Date 2/4/09 Arrival Time _____ Departure Time _____

2. PERSONNEL

NA Pharmacist on duty License No. Expiration Date

(Attach list)

3. SECURITY

Yes No

☐NA☐ a. Is a pharmacist always immediately available on the premises to provide services at all times that the pharmacy is open? (COMAR 10.34.05.03)

☑ ☐ b. Are policies and procedures in place for emergency access to the facility. ~~pharmacy~~ when closed and a pharmacist is not available? (COMAR 10.34.05.02 B (3))

☑ ☐ c. Are there provisions to prevent individuals from having access to the ~~prescription~~ Distribution area ~~when a pharmacist is not present? (COMAR 10.34.05.02 A(3))~~

4. Record Keeping Requirements

Yes	No		
☐	☐	a.	Is the paper DEA Form 222 utilized? NA - No schedule II drugs are shipped
☐	☐	b.	If yes to the above, are DEA Form 222s maintained separately from other records and kept available for 2 years? (21 CFR 1305.17)
☐	☐	c.	Are powers of attorney authorizing individuals to order Schedule II drugs on file? (21CFR 1305.05)
☐	☐	d.	Are DEA Form 222 orders signed and dated by a person authorized by a power of attorney? (21 CFR 1305.05)
☐	☐	e.	Does the purchaser record, for each line item on DEA Form 222, the quantity received and the date received? (21 CFR 1305.13(e))
☐	☐	f.	Are Schedule II products ordered using CSOS (controlled substance ordering system)?
☐	☐	g.	If yes to above, is each electronic order linked to a record created to show the quantity received and the date received by the purchaser? (21 CFR 1305.22 (g))
☐	☐	h.	Are CDS provided to practitioners for office use or to institutions as stock supply? If so who _____
☐	☐	i.	If yes to above, is this distribution done using a DEA Form 222 for Schedule II products or a purchase order for Schedule III – V products? (21 CFR 1307.11)
☑	☐	j.	Are receipts and invoices for Schedule III – V CDS being dated? (21 CFR 1304.21)
☑	☐	k.	Is the Biennial Inventory of CDS being taken and maintained as required? (COMAR 10.19.03.05 B) Date 5-1-08 Time _____ By whom Authorized individuals.
☐	☐	l.	Are Schedule II CDS surrendered for disposal done using DEA Form 222?
☐	☐	m.	Are transfers of Schedule II CDS between pharmacies done using DEA Form 222? (21 CFR 1305.03)

NA

NA

5. Prescription Records

Yes	No		
☐	☐	a.	Is the practitioner's name, address and DEA number on CDS prescriptions? (21 CFR 1306.05(a)
☐	☐	b.	Is the patient's name and address on CDS prescriptions? (21 CFR 1306.05(a))
☐	☐	c.	Are prescriptions for Schedule II CDS written in ink, indelible pencil, typewriter or computer and manually signed (pen to paper) and dated by the practitioner? (COMAR 10.19.03.07D(1))
☐	☐	d.	Are prescriptions for Schedule II CDS dispensed within 120 days of the date of issue? (COMAR 10.19.03.08 A (8))

NA

☐ ☐ e. Does pharmacy accept prescriptions for Schedule III – V CDS signed electronically? (COMAR 10.19.03.09A(1))

☐ ☐ f. If yes to the above, are the prescriptions verified and documentation made?

☐ ☐ g. Do facsimile prescriptions for Schedule II CDS serve as the original written prescription only for patients receiving substances compounded for direct administration by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion or residing in a Long Term Care facility or a hospice certified by Medicare under Title XVIII? (COMAR 10.19.03.08A(6) or (7))

NA

☐ ☐ h. Does the pharmacy ensure that the original prescription for emergency oral or fax prescriptions for Schedule II CDS is postmarked within 7 days after dispensing an emergency oral or fax prescription and is attached to the copy of the prescription? (21 CFR 1306.11(d)(4))

☐ ☐ i. Does the pharmacy provide long term care or assisted living facilities with CDS products?

6. Security Controls and CDS Loss Reporting

Yes No

☑ ☐ a. Does the pharmacy use a perpetual inventory system for Schedule ~~II~~ III - V CDS?
How often is it verified? Weekly By whom? Scheduled Personnel.

☐ ☐ b. If yes to the above, is there a policy for reconciliation of any difference in the perpetual inventory count and the actual count of Schedule ~~II~~ III - V CDS?
Who reviews any discrepancy found? pharmacist

☑ ☐ c. Is any significant loss of any CDS, upon discovery of such a loss or theft, reported to the regional office of the DEA and the Division of Drug Control (DDC) using DEA Form 106? (COMAR 10.19.03.12B(4))
Who makes the decision on what is significant? Any discrepancy is reported

☑ ☐ d. Does the pharmacy provide effective controls and procedures to guard against theft and unlawful diversion of CDS? (COMAR 10.19.03.12A(1))

☑ Background checks ☑ Drug testing ☑ Inventory system ☑ Perpetual inventory verification ☑ Alarms ☑ Video cameras ☐ Reporting loss/theft ☑ Access to CDS ☑ Supervision of employees handling CDS

NA ☐ ☐ e. Are Schedule II CDS:
☐ ☐ stored in a securely locked, substantially constructed cabinet
☐ ☐ dispursed throughout the stock of noncontrolled items?
(COMAR 10.19.03.12 B(2)

7. CDS Compounding

NA

Yes	No		
☐	☐	a.	Does the pharmacy do compounding using CDS?
☐	☐	b.	Are any CDS compounded products essential copies of commercially available drug products? (21 USCS 353a.(b)(D)
☐	☐	c.	If yes to the above, does the product which is produced for an individual patient, provide a significant difference, as determined by the prescriber, between the compounded drug and the comparable commercially available product? (21 USCS353a.(b)(D)(2))

8. Internet Pharmacy Service

NA

☐	☐	a.	Does the pharmacy engage in internet pharmacy?
☐	☐	b.	If yes to the above, is the practice through an agreement with an intermediary? Who is the intermediary? _____
☐	☐	c.	Do you accept prescriptions for CDS from the intermediary?
☐	☐	d.	Do you accept prescriptions for non-controlled prescription drugs and devices from the intermediary? Which ones _____
☐	☐	e.	Do all CDS prescriptions from the intermediary bear a prescriber's manual signature or a facsimile of a manually written signature?
☐	☐	f.	Are the prescriptions for CDS issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's professional practice? (21 CFR 1306.04(a)), COMAR 10.19.03.07 C (1)
☐	☐	g.	Are prescriptions mailed out of state?
☐	☐	h.	If yes to the above, is the pharmacy registered with each state to which prescriptions are mailed? List states in which registered: _____

Inspection Summary

Inspector comments and recommendations:

Distribution Center Serves approximately 2,200 stores for all items. Except C II drugs. Conducted meeting with the following personnel. Tim Pebley, General Manager; William Merrow Senior Operations Manager, Joyce Speitzer Senior Manager of Loss Prevention Kimberly Brown Rx Dept Manager, Mariam Lodod DEA Coordinator.

Reviewed Report of Theft/Loss DEA 106 for FY 2018-07
Discussed various methods to determine the source of theft or loss and attempt to pin point the weak link in the distribution chain from manufacturer/distributor Through Carriers such as FedEx, UPS etc. Number of theft/loss report. Rite Aid Mid Atlantic Ships approximately 7 million units of CDS per year.

Actions required by this report:
(1) Please identify carrier tracking number.

Date required action must be completed: _____

Name of CDS registrant or designee: TIMOTHY J. PEIFLEY (print)

Signature of CDS registrant or designee: _____

Inspector: CHANDRA K. MOULI (print)

Signature: Chandra K Mouli

STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, Secretary

Division of Drug Control
4201 Patterson Avenue
Baltimore, Maryland 21215
410-764-2890

Controlled Dangerous Substances (CDS)
Establishment Inspection Report

1. PERMITS AND LICENSES:

Establishment Classification Distribution
Establishment Name Rite Aid Mid-Atlantic Customer Center
Address 601 Chelsea Rd City Aberdeen Zip 21001
Telephone 410-297-6334 Fax. 410-297-6049 County: Harford CO
Establishment Registration/Permit Number D01005 Expiration 12-31-2012
Maryland CDS Registration Number 244950 Expiration 10-31-2013
DEA Registration Number [redacted] Expiration 4-30-2013
DEA Registrant General Manager
Establishment Hours of Operation: M-F 7-5 Sat. 7-5 Sun. C Hol.
Inspection Date 8-21-2012 Arrival Time 11:00 Departure Time 1:45

2. PERSONNEL:

Personnel on duty	License No. (if applicable)	Expiration Date
Marian Wood. DEA Coordinator		

3. RECORD KEEPING REQUIREMENTS:

No scheduled II drugs ordered.

Yes	No		
☐	☐	a.	Is the paper DEA Form 222 utilized?
☐	☐	b.	If yes to the above, are DEA Form 222s maintained separately from other records and kept available for 2 years? (21 CFR 1305.17)
☐	☐	c.	Are powers of attorney authorizing individuals to order Schedule II drugs on file? (21CFR 1305.05)

NA

Yes No

NA

- ☐ ☐ d. Are DEA Form 222 orders signed and dated by registrant or a person authorized by a power of attorney? (21 CFR 1305.05)
- ☐ ☐ e. Does the purchaser record, for each line item on DEA Form 222, the quantity received and the date received? (21 CFR 1305.13(e))
- ☐ ☐ f. Are Schedule II products ordered using CSOS (controlled substance ordering system)?
- ☐ ☐ g. If yes to above, when an order is received, is a record created of the quantity of each item received and the date received, and is this record electronically linked to the original order and archived? (21 CFR 1305.22 (g))
- ☐ ☒ h. Are CDS provided to the establishment by a pharmacy?
  If so, name of pharmacy _____
- ☐ NA i. If yes to above, are these transactions done using a DEA Form 222 for Schedule II products or a purchase order for Schedule III – V products? (21 CFR 1307.11)
- ☑ ☐ j. Are receipts and invoices for Schedule III – V CDS being dated upon receipt? (21 CFR 1304.21)
- ☑ ☐ k. Is the Biennial Inventory of CDS being taken and maintained as required? (COMAR 10.19.03.05 B)
  Date 5-1-2012 (Open)/ Close of business By whom Marian Wood.
- ☐ NA l. Are Schedule II CDS surrendered for disposal done using DEA Form 222?
  If yes, name of reverse distributor used ~~Mariar~~ n/a
- ☐ NA m. Are transfers of Schedule II CDS made between establishments?
- ☐ NA n. If yes, is a DEA-222 form used when transfers are made? (21 CFR 1305.03)

4. SECURITY CONTROLS AND CDS LOSS REPORTING:

Yes No

- ☑ ☐ a. Does the establishment use a perpetual inventory system for Schedule ~~II~~ III-V CDS?
  How often is it verified? Weekly By whom? Scheduled Personnel.
- ☑ ☐ b. If yes to the above, is there a policy for reconciliation of any difference in the perpetual inventory count and the actual count of Schedule ~~II~~ III-V CDS?
  Who reviews any discrepancy found? Marian Wood.
- ☑ ☐ c. Is any significant loss of any CDS, upon discovery of such a loss or theft, reported to the regional office of the DEA and the Division of Drug Control (DDC) using DEA Form 106? (COMAR 10.19.03.12B(4))
  Who makes the decision on what is significant? Marian Wood.
- ☑ ☐ d. Does the establishment provide effective controls and procedures to guard against theft and unlawful diversion of CDS? (COMAR 10.19.03.12A(1))

  ☑ Background checks ☑ Drug testing ☑ Alarms ☑ Video cameras ☑ Access to CDS limited through electronic badge
- ☑ ☐ e. Are all CDS stored in a securely locked, substantially constructed cabinet? (COMAR 10.19.03.12 B(1-2))
- ☑ ☐ f. Is the registrant or designee always immediately available on the premises to provide services at all times that the establishment is in operation?

5. CDS DISPOSITION RECORDS:

6. INVENTORY OF SCHEDULE II PRODUCTS: as of _____

Drug Name/Strength/Form	Count	Perpetual Inventory
1. No Schedule II. drugs		
2. on premises.		
3.		
4.		

Count performed by: _____

Counts do / do not include CII orders received on _____

7. INSPECTION SUMMARY:

Inspector comments and recommendations:
The facility has a good system for receipt and accountability of CDS. All significant loss of CDS upon receipt of shipment are promptly reported and follow up action with the vendors are documented.

Actions required by this report:
None.

8. REQUIRED ACTION DATE AND REPORT SIGNATURES:

Date required action must be completed: -

Name of registrant or designee: MARIAN WOOD (print)

Signature of registrant or designee: Marian Wood

Inspector: CHANDRA K. MOULI (print)

Signature: Chandra K Mouli

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8/16/2011

Exhibit K

Copy

CLOSING INVENTORY

REGISTRANT
Rite Aid

DEA# [redacted]

DATE TAKEN 11/17/2014 (CT/EST) (COB)

BY Smoak / Reed

	DRUG	AMOUNT
0108315	1. Hydrocodone IAPAP 5/325mg tablets	Ø
0107958	2. Vicoden ES 7.5/300mg tablets	Ø
0106388	3. Buprenorphine 8mg tablets	Ø
0603690	4. Suboxone 8mg/2mg SL film	Ø
0128437	5. Alprazolam 2mg tablets	Ø
0128438	6. Carisoprodol 350mg tablets	Ø
0601280	7. Lyrica 150mg capsules	Ø
0602004	8. Promethazine VC w/Cod 10mg/5oz bts.	Ø
	9.	

I, _____ having signed my name below, concur with the above inventory taken on this date

Signed _____

Date 11/17/2014

WITNESSED

Monica Smoak, DI 11/17/14

Will Reed, DI 11-17-14